

US3912076 (Prod: Synexus - Optimal Research - Austin)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:22:38

All time stamps listed in this document are displayed in GMT

US3912076

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:13:38

Generated On: 10 Jun 2021 10:22:38

[Participant ID](#)

US3912076

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

US3912076

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3912076

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
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

US3912076

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	2 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

US3912076

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3912076

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Were any significant conditions reported?

Yes ☒

No ☐

US3912076

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Mar 2021 16:22:47

Generated On: 10 Jun 2021 10:22:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3912076

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Mar 2021 16:22:47

Generated On: 10 Jun 2021 10:22:38

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

US3912076

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Mar 2021 16:22:47

Generated On: 10 Jun 2021 10:22:38

Condition	THYROIDECTOMY
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

US3912076

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Mar 2021 16:22:47

Generated On: 10 Jun 2021 10:22:38

Condition	GOITER
Start date (dd MMM yyyy)	UN UNK 1987
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 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

US3912076

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Mar 2021 16:22:47

Generated On: 10 Jun 2021 10:22:38

Condition	ASTHMA - MODERATE
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

US3912076

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Mar 2021 16:22:47

Generated On: 10 Jun 2021 10:22:38

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3912076

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Mar 2021 16:22:47

Generated On: 10 Jun 2021 10:22:38

Condition	CHF
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3912076

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:37 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 09:37
Height (<i>xxx.x</i>)	59.5 in
Weight (<i>xxx.x</i>)	197 lb
BMI (<i>xxx.x</i>)	39.20507 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912076

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3912076

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Date of assessment (dd MMM yyyy) 02 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) UN UNK 2009

Date of last menstruation unknown False

US3912076

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145282

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 ☒

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Height	ND - Not Done
Weight	ND - Not Done

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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)	02 SEP 2020
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 09:37
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 12:53
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3912076

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 12:14 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 12:14

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

US3912076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

11:03 (24 HR)

Collection date and time (derived)

02 SEP 2020 11:03

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:07	02 SEP 2020 11:07
Nasopharyngeal Swab 2	No		

US3912076

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:57

PC Open Date & Time

02 SEP 2020 12:34

PC Close Date & Time

02 SEP 2020 15:04

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp	02 SEP 2020 18:54
PC Open Date & Time	02 SEP 2020 15:59
PC Close Date & Time	03 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

04 SEP 2020 03:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

05 SEP 2020 17:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

06 SEP 2020 12:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:24

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 14:11

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

02 SEP 2020 12:57

PC Open Date & Time

02 SEP 2020 12:34

PC Close Date & Time

02 SEP 2020 15:04

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

02 SEP 2020 18:55

PC Open Date & Time

02 SEP 2020 15:59

PC Close Date & Time

03 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 03:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

04 SEP 2020 12:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

05 SEP 2020 17:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

06 SEP 2020 12:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

07 SEP 2020 12:25

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

08 SEP 2020 14:12

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 12:58
PC Open Date & Time	02 SEP 2020 12:34
PC Close Date & Time	02 SEP 2020 15:04

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 18:56
PC Open Date & Time	02 SEP 2020 15:59
PC Close Date & Time	03 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 03:39
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:45
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 17:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

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 ☒

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:25
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

59 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 14:12
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3912076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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

Visit date (dd MMM yyyy)	30 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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)	30 SEP 2020
Time of assessment (00:00-23:59)	09:53 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:53
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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)	30 SEP 2020
Time of assessment (00:00-23:59)	11:41 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:41
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3912076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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) 30 SEP 2020

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

Treatment Date and Time (derived) 30 SEP 2020 11:00

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

US3912076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

10:32 (24 HR)

Collection date and time (derived)

30 SEP 2020 10:32

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:36	30 SEP 2020 10:36
Nasopharyngeal Swab 2	No		

US3912076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 11:43

PC Open Date & Time

30 SEP 2020 11:20

PC Close Date & Time

30 SEP 2020 13:50

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp 30 SEP 2020 15:15

PC Open Date & Time 30 SEP 2020 14:45

PC Close Date & Time 01 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 18:44

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

02 OCT 2020 13:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

03 OCT 2020 17:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

04 OCT 2020 13:11

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

07 OCT 2020 07:50

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 11:43

PC Open Date & Time

30 SEP 2020 11:20

PC Close Date & Time

30 SEP 2020 13:50

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

30 SEP 2020 15:16

PC Open Date & Time

30 SEP 2020 14:45

PC Close Date & Time

01 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

01 OCT 2020 18:44

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

02 OCT 2020 13:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

03 OCT 2020 17:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

04 OCT 2020 13:12

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

07 OCT 2020 07:50

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 11:44
PC Open Date & Time	30 SEP 2020 11:20
PC Close Date & Time	30 SEP 2020 13:50

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 15:16
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PC Open Date & Time	30 SEP 2020 14:45
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PC Close Date & Time	01 OCT 2020 11:59
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US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

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 ☒

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 18:45
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 13:02
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 17:49
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 13:12
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

103 of 2703

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

105 of 2703

EAB) (1725)

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 07:50
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3912076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	15:56 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 15:56
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

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.

US3912076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

16:10 (24 HR)

Collection date and time (derived)

28 OCT 2020 16:10

US3912076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

02 NOV 2020 03:00:14

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

09 NOV 2020 06:08:51

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 02:03:28

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 NOV 2020 18:03:53
Patient Cloud Open Date & Time	20 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
121 of 2703	

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 NOV 2020 08:17:48
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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



Date and time of submission	04 DEC 2020 02:27:11
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

11 DEC 2020 03:07:32

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 08:00:58

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

25 DEC 2020 16:56:25

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☒

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 14:08:11

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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	08 JAN 2021 17:35:37
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

15 JAN 2021 05:19:09

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 02:11:33
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 FEB 2021 08:49:27
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

05 FEB 2021 04:42:12

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 FEB 2021 12:20:13
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

19 FEB 2021 07:14:36

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 06:43:11
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

07 MAR 2021 20:40:08

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 07:16:50

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 12:45:13

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 15:04:07

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

02 APR 2021 00:24:54

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

09 APR 2021 12:56:01

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

19 APR 2021 11:18:49

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

27 APR 2021 10:46:34

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 00:16:45

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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°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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐ 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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐ 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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Patient Cloud Open Date & Time	08 OCT 2021 00:01
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Patient Cloud Close Date & Time	12 OCT 2021 23:59
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US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐ 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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 502

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

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

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

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

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 530

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

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

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

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

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

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

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

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08 MAR 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

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15 MAR 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Patient Cloud Open Date & Time	25 MAR 2022 00:01
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Patient Cloud Close Date & Time	29 MAR 2022 23:59
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US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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°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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 698

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

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

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

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

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

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

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐ 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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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="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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐ 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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 754

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

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

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

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

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐ 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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:22:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 09:41:13

US3912076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 19:54:33

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:54:33

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 22:47:30

Generated On: 10 Jun 2021 10:22:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:50:42

Generated On: 10 Jun 2021 10:22:38

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) _____

US3912076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 22:47:30

Generated On: 10 Jun 2021 10:22:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3912076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 22:47:30

Generated On: 10 Jun 2021 10:22:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	08:55 (24 HR)
Collection date and time (derived)	24 MAR 2021 08:55

US3912076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:47:30

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

Date of Contact	23 NOV 2020
Time of Contact	15:08
Date and Time of Contact (derived)	23 NOV 2020 15:08
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

323 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	23 NOV 2020
------	-------------

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

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

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

Temperature	36.9 C
-------------	--------

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

327 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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)

328 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	24 NOV 2020
------	-------------

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

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

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

Temperature	36.6 C
-------------	--------

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

331 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	25 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	36.8 C
-------------	--------

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 type="radio"/>
	Mild	<input checked="" 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"/>

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EAB) (1725)

335 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	36.9 C	
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 type="radio"/>
	Mild	<input checked="" 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

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339 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	36.8 C	
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)

343 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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)

344 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	28 NOV 2020
------	-------------

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

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

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

Temperature	37.1 C
-------------	--------

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

347 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	29 NOV 2020
------	-------------

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

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

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

Temperature	36.6 C
-------------	--------

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

351 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	30 NOV 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 type="radio"/>
	Mild	<input checked="" 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)

355 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	01 DEC 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 type="radio"/>
	Mild	<input checked="" 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)

359 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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	02 DEC 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	36.8 C
-------------	--------

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)

363 of 2703

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

	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"/>

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 16:13:42

Generated On: 10 Jun 2021 10:22:38

Date of Visit	23 NOV 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	23 NOV 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)	0

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 16:14:15

Generated On: 10 Jun 2021 10:22:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 NOV 2020
Day 5	Yes	27 NOV 2020
Day 7	Yes	29 NOV 2020
Day 9	Yes	01 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3912076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

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

Visit date (dd MMM yyyy)	23 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	SICKD1
------------	--------

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 15:16
Height (xxx.x)	60.0 in
Weight (xxx.x)	203.0 lb
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3912076

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

US3912076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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 _____

US3912076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

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.

US3912076

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 10:22:38

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3912076

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

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

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3912076

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

Form: Unblinding

Data signed: (b) (4) 31 Mar 2021 17:50:42

Generated On: 10 Jun 2021 10:22:38

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3912076

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

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

US3912076

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 13:09
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	11 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3912076

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 15:20
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3912076

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

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.

US3912076

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 13 JAN 2021

What was the treatment time? (00:00-23:59) 14:35 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 14:35

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

US3912076

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

12:32 (24 HR)

Collection date and time (derived)

13 JAN 2021 12:32

US3912076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	12:35
Collection Date and Time (derived)	13 JAN 2021 12:35

US3912076

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:14:16

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:14:17

Generated On: 10 Jun 2021 10:22:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 21:29:01

Generated On: 10 Jun 2021 10:22:38

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

OLD29 Placebo Flag

US3912076

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 16:13:38

Generated On: 10 Jun 2021 10:22:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

AEID

Adverse event

LACERATION TO LIP

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

390 of 2703

EAB) (1725)

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

AEID	USA-US211-2021-MRNA-1273-P30 1000001
Adverse event	ACUTE ANAPHYLAXIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
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 checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2703

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

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	

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

SUBJECT HAD AN ALLERGIC
REACTION TO UNKNOWN
ALLERGEN AND WAS TREATED
AND RELEASED FROM
EMERGENCY ROOM.

SUBJECT PRESENTED TO ER
WITH COMPLAINTS OF
URTICARIA, PRURITIS AND
THROAT SWELLING. SHE
STATED THAT HER THROAT
FELT SWOLLEN AND WAS
HAVING SEVERE DYSPNEA
AND CHEST TIGHTNESS. UPON
EXAMINATION, IT WAS NOTED
THAT SHE APPEARED ILL AND
IN DISTRESS; SHE WAS
TACHYCARDIC, HAD AUDIBLE
WHEEZING BUT NO LIP OR
TONGUE SWELLING. THERE
WAS NO OROPHARYNGEAL OR
LIP SWELLING; SKIN EXAM
POSITIVE FOR DIFFUSE
URTICARIA.

SHE WAS TREATED WITH IM
EPIPEN UPON ARRIVAL;
IMMEDIATELY THROAT
SWELLING AND CHEST PAIN
HAD RESOLVED. SINCE THE
SUBJECT DID NOT HAVE A
HISTORY OF ANAPHYLAXIS,
SHE WAS OBSERVED FOR 3
HOURS TO ENSURE NO
REBOUND ANAPHYLAXIS AND
WAS LATER DISCHARGED IN
STABLE CONDITION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

AEID

Adverse event

INSULIN DEPENDENT
DIABETES MELLITUS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

395 of 2703

EAB) (1725)

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

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 type="radio"/> Not Applicable <input checked="" 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

AEID

Adverse event

WORSENING OF ASTHMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

397 of 2703

EAB) (1725)

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 02 Apr 2021 15:35:44

Generated On: 10 Jun 2021 10:22:38

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

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 16:13:42

Generated On: 10 Jun 2021 10:22:38

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

Yes ☒

No ☐

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

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication AMLODIPINE/OLMESARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

400 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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 AUG 2019	
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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication CARDIZEM

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 120

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)

402 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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 AUG 2019	
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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 150

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

If dose unit is Other, specify MCG

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

404 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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 1991	
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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

406 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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 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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication SINGULAIR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

408 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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 2019	
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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify SOLUTION

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 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication EPIPEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

Dose per administration 0.3

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

412 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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)		31 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication ALBUTEROL 0.083%

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

414 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 31 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

Dose per administration 20

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)

416 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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 checked="" 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)		31 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

Dose per administration 125

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

418 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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 checked="" 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)		31 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication EPINEPHRINE HCL

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

Dose per administration 0.3

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

420 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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)		31 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

Dose per administration 25

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)

422 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication PEPCID

Prophylaxis Yes ☒
No ☐

Indication GI PROPHYLAXIS

Dose per administration 20

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)

424 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

Dose per administration 20

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

426 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 FEB 2021		
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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication POST ACUTE ANAPHYLAXIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

428 of 2703

EAB) (1725)

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 2 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication ALBUTEROL SULFATE
INHALER

Prophylaxis Yes ☐
No ☒

Indication ACUTE ANAPHYLAXIS

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)

430 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)	1 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication FIASP (INSULIN ASPART)
BEFORE MEALS

Prophylaxis Yes ☐
No ☒

Indication INSULIN DEPENDENT DIABETIC
MELLITUS

Dose per administration 10-15

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)

432 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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)	13 FEB 2021	
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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication TRESIBA (INSULIN100U/ML
LONG ACTING AT BEDTIME)

Prophylaxis Yes ☐
No ☒

Indication INSULIN DEPENDENT DIABETIC
MELLITUS

Dose per administration 25

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)

434 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
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"/>

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

Name of Medication PREDNISONONE (5MG TAPERED DOSE)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF ASTHMA

Dose per administration 60

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)

436 of 2703

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 01 Apr 2021 22:14:31

Generated On: 10 Jun 2021 10:22:38

	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)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 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"/>

US3912076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 16:13:42

Generated On: 10 Jun 2021 10:22:38

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3912076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 16:13:42

Generated On: 10 Jun 2021 10:22:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 JAN 2021	2 STITCHES TO LIP	Adverse Event	

US3912076

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:22:38

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 ☐

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 09 Mar 2021 19:54:33

Generated On: 10 Jun 2021 10:22:38

SAEID	USA-US211-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Mar 2021 19:54:33

Generated On: 10 Jun 2021 10:22:38

SAEID	USA-US211-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/FEB/2021 14:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Mar 2021 19:54:33

Generated On: 10 Jun 2021 10:22:38

SAEID	USA-US211-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/FEB/2021 14:35
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

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Mar 2021 19:54:33

Generated On: 10 Jun 2021 10:22:38

SAEID	USA-US211-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/FEB/2021 14:58
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

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Mar 2021 19:54:33

Generated On: 10 Jun 2021 10:22:38

SAEID	USA-US211-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/MAR/2021 09:49
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

US3912076 (Prod: Synexus - Optimal Research - Austin)

US3912076

Form: Participant Creation

Generated On: 10 Jun 2021 10:22:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'US3912076'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:15:05

US3912076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:18
	(b) (4)	

US3912076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '02 SEP 2020'	RWS_ENDPOINT	02 Sep 2020 14:15:06
	ENDPOINT (b) (4)	

US3912076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[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 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:18
	(b) (4)	

US3912076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered 'SCRN'	System	02 Sep 2020 16:55:18

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered (b) (6) 1969'	RWS_ENDPOINT	02 Sep 2020 14:15:08
	ENDPOINT (b) (4)	

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '51'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'YEARS'	System	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '51'	System	02 Sep 2020 16:55:33

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:27:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:27:08
User entered 'Female (F)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:27:08
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:26:27
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:26:27

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '2 Sep 2020'	Tina Rountree (b) (4)	02 Sep 2020 16:55:33
	(b) (4)	

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Sep 2020'	System	02 Sep 2020 16:55:33

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '2020'	System	02 Sep 2020 16:55:33

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Amendment 3 (3)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:33
	(b) (4)	

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:33
	(b) (4)	

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	02 Sep 2020 16:55:33
	(b) (4)	

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	02 Sep 2020 16:55:33
	(b) (4)	

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:33
	(b) (4)	

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	RWS_ENDPOINT	02 Sep 2020 14:15:06
	ENDPOINT (b) (4)	

US3912076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1'	System	02 Sep 2020 16:55:40

US3912076

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:40
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:22:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:39:41
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:42:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:42:35
	(b) (4)	
Data point term sent to Coder	System	07 Sep 2020 00:41:44
User entered 'Hypertension'	Tina Rountree (b) (4)	07 Sep 2020 00:41:04
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'un UNK 2008'	Tina Rountree (b) (4)	07 Sep 2020 00:41:04
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:41:04
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:41:04
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:41:04
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:41:04
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 2008'	System	07 Sep 2020 00:41:04

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '2008'	System	07 Sep 2020 00:41:04

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:41:04

US3912076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:41:04

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:42:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:42:35
	(b) (4)	
Data point term sent to Coder	System	07 Sep 2020 00:41:42
User entered 'hypothyroidism'	Tina Rountree (b) (4)	07 Sep 2020 00:41:26
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'un UNK 1987'	Tina Rountree (b) (4)	07 Sep 2020 00:41:26
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:41:26
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:41:26
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:41:26
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:41:26
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 1987'	System	07 Sep 2020 00:41:26

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1987'	System	07 Sep 2020 00:41:26

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:41:26

US3912076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:41:26

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:43:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:43:36
	(b) (4)	
Data point term sent to Coder	System	07 Sep 2020 00:42:44
User entered 'thyroidectomy'	Tina Rountree (b) (4)	07 Sep 2020 00:42:27
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'UN UNK 1991' reason for change:	Tina Rountree (b) (4)	07 Sep 2020 00:44:12
Data Entry Error	(b) (4)	
User entered 'un Nov 1991'	Tina Rountree (b) (4)	07 Sep 2020 00:42:27
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:42:27
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:42:27
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Sep 2020 00:44:12
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	07 Sep 2020 00:42:27
User entered 'un UNK 1991'	Tina Rountree (b) (4)	07 Sep 2020 00:42:27
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:42:27
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 1991'	System	07 Sep 2020 00:44:12
User entered 'Nov 1991'	System	07 Sep 2020 00:42:27

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1991'	System	07 Sep 2020 00:42:27

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 1991'	System	07 Sep 2020 00:42:27

US3912076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1991'	System	07 Sep 2020 00:42:27

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Goiter - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:44:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:44:36
	(b) (4)	
Data point term sent to Coder	System	07 Sep 2020 00:43:47
User entered 'goiter'	Tina Rountree (b) (4)	07 Sep 2020 00:43:01
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'un UNK 1987'	Tina Rountree (b) (4)	07 Sep 2020 00:43:01
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:43:01
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	07 Sep 2020 00:44:45
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	07 Sep 2020 00:44:45
	(b) (4)	
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	07 Sep 2020 00:43:01
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:43:01
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'UN UNK 1991' reason for change:	Tina Rountree (b) (4)	07 Sep 2020 00:44:36
Data Entry Error	(b) (4)	
User entered 'un UNK 1987'	Tina Rountree (b) (4)	07 Sep 2020 00:43:01
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:43:01
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 1987'	System	07 Sep 2020 00:43:01

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1987'	System	07 Sep 2020 00:43:01

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 1991'	System	07 Sep 2020 00:44:36
User entered 'Jan 1987'	System	07 Sep 2020 00:43:01

US3912076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1991'	System	07 Sep 2020 00:44:36
User entered '1987'	System	07 Sep 2020 00:43:01

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User closed query 'Please clarify whether asthma is mild, moderate or severe. Thanks!' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 19:57:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 14:18:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 14:18:44
Data point term sent to Coder	System	03 Oct 2020 14:18:06
Query 'Please clarify whether asthma is mild, moderate or severe. Thanks!' answered with 'added moderate' (Site from CRA).	Tina Rountree (b) (4)	03 Oct 2020 14:17:21
Coding entries removed.	Tina Rountree (b) (4)	03 Oct 2020 14:17:14
User entered 'ASTHMA - moderate' reason for change: Data Entry Error	Tina Rountree (b) (4)	03 Oct 2020 14:17:14
User opened query 'Please clarify whether asthma is mild, moderate or severe. Thanks!' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 20:17:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 00:44:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 00:44:36
Data point term sent to Coder	System	07 Sep 2020 00:43:47
User entered 'asthma'	Tina Rountree (b) (4)	07 Sep 2020 00:43:24

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'un UNK 2004'	Tina Rountree (b) (4)	07 Sep 2020 00:43:24
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:43:24
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:43:24
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:43:24
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:43:24
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 2004'	System	07 Sep 2020 00:43:24

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '2004'	System	07 Sep 2020 00:43:24

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:43:24

US3912076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:43:24

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:44:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 00:44:36
	(b) (4)	
Data point term sent to Coder	System	07 Sep 2020 00:43:45
User entered 'post menopausal'	Tina Rountree (b) (4)	07 Sep 2020 00:43:44
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'un UNK 2009'	Tina Rountree (b) (4)	07 Sep 2020 00:43:44
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:43:44
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:43:44
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:43:44
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:43:44
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 2009'	System	07 Sep 2020 00:43:44

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '2009'	System	07 Sep 2020 00:43:44

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:43:44

US3912076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	07 Sep 2020 00:43:44

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).		12 Apr 2021 03:49:44
Query 'Per DM CLR: Please note that there is no Con Sandra Clancy Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'correct - con meds would be expected but none are noted in medical records and subject denies this condition; when asked about it she said she has taken lasix but she does not offer more detail.' (Site from DM).	(b) (4) (b) (4)	08 Apr 2021 16:42:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 04:10:04
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 13:47:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 13:47:49
Data point term sent to Coder	System	26 Mar 2021 13:47:35
User entered 'CHF'	Mia Rountree (b) (4) (b) (4)	26 Mar 2021 13:47:32

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
	(b) (4)	
User entered 'un UNK 2008'	Mia Rountree (b) (4)	26 Mar 2021 13:47:32
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
	(b) (4)	
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:47:32
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
	(b) (4)	
User entered 'Yes (Y)'	Mia Rountree (b) (4)	26 Mar 2021 13:47:32
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:47:32
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
	(b) (4)	
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:47:32
	(b) (4)	

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'Jan 2008'	System	26 Mar 2021 13:47:32

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '2008'	System	26 Mar 2021 13:47:32

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	26 Mar 2021 13:47:32

US3912076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	26 Mar 2021 13:47:32

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '02 Sep 2020'	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '09:37'	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered '02 Sep 2020 09:37'	System	07 Sep 2020 00:45:52

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '59.5' in	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	
DataPoint set to visible.	System	02 Sep 2020 16:55:40

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '197' lb	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	
DataPoint set to visible.	System	02 Sep 2020 16:55:40

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered '39.20507'	System	07 Sep 2020 00:45:52
DataPoint set to visible.	System	02 Sep 2020 16:55:40

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered 'kg/m2'	System	07 Sep 2020 00:45:52
DataPoint set to visible.	System	02 Sep 2020 16:55:40

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered 'bpm'	System	07 Sep 2020 00:45:52

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered 'breaths/min'	System	07 Sep 2020 00:45:52

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered 'mmHg'	System	07 Sep 2020 00:45:52

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	07 Sep 2020 00:45:52
	(b) (4)	

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User entered 'mmHg'	System	07 Sep 2020 00:45:52

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03

US3912076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03

US3912076

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:46:05
	(b) (4)	

US3912076

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '02 Sep 2020'	Tina Rountree (b) (4)	07 Sep 2020 00:46:05
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '02 Sep 2020'	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'un UNK 2009'	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:22:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:46:56
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

[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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

[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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 00:47:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Sep 2020 00:47:52
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	07 Sep 2020 00:47:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Sep 2020 00:47:43
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

[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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'I'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:47:43
	(b) (4)	

US3912076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:51

US3912076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '2 Sep 2020'	(b) (4) Tina Rountree (b) (4)	02 Sep 2020 16:55:51

US3912076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[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 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	02 Sep 2020 16:55:51

US3912076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'VISIT1'	System	02 Sep 2020 16:55:51

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:49

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '145282'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:49

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:05:49

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

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 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:53:54
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'entered' (Site from DM).	Tina Rountree (b) (4)	07 Sep 2020 00:49:25
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:49:19
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 14:49:28

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

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 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:49:19

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:49:19

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:49:19

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:49:19

US3912076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:38:33
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Data entered' (Site from DM).	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 14:11:58
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 14:10:57
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 14:21:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:51:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:51:52

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done.	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done.	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User accepted default value 'Pre-Dose (PREDOSE)'	Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '02 Sep 2020'	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '09:37'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered '02 Sep 2020 09:37'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '37.1' C	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Oral (Oral)'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '71'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'bpm'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '16'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'breaths/min'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '129'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'mmHg'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '89'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'mmHg'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done.	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done.	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User accepted default value 'Post-Dose (POSTDOSE)'	Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '02 Sep 2020'	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '12:53'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered '02 Sep 2020 12:53'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.9' C	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Oral (Oral)'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '74'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'bpm'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '15'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'breaths/min'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '128'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'mmHg'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '86'	Tina Rountree (b) (4)	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'mmHg'	System	07 Sep 2020 00:52:05

US3912076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:52:43

US3912076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '02 Sep 2020'	Tina Rountree (b) (4)	07 Sep 2020 00:52:43

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '2 Sep 2020'	Tina Rountree (b) (4)	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '12:14'	Tina Rountree (b) (4)	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered '2 Sep 2020 12:14'	System	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4)	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'ONCE'	System	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 17:17:39

US3912076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:53:30

US3912076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '02 Sep 2020'	Tina Rountree (b) (4)	07 Sep 2020 00:53:30

US3912076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '11:03'	Tina Rountree (b) (4)	07 Sep 2020 00:53:30

US3912076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered '02 Sep 2020 11:03'	System	07 Sep 2020 00:53:30

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:22:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '02 Sep 2020'	Tina Rountree (b) (4)	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '11:07'	Tina Rountree (b) (4)	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered '02 Sep 2020 11:07'	System	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered empty.	System	07 Sep 2020 00:53:52

US3912076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:53:56

US3912076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	07 Sep 2020 00:53:56

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6c5e4f51-d8e0-4829-b811-50e24cb4f784'	System	02 Sep 2020 17:57:29
User entered 'Yes (Y)'	System	02 Sep 2020 17:57:29

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:11', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6c5e4f51-d8e0-4829-b811-50e24cb4f784'	System	02 Sep 2020 17:57:29
User entered '98.5'	System	02 Sep 2020 17:57:29

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6c5e4f51-d8e0-4829-b811-50e24cb4f784'	System	02 Sep 2020 17:57:29
User entered 'No (N)'	System	02 Sep 2020 17:57:29

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:27', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6c5e4f51-d8e0-4829-b811-50e24cb4f784'	System	02 Sep 2020 17:57:29
User entered '02 Sep 2020 12:57'	System	02 Sep 2020 17:57:29

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 12:34'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 15:04'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:54:35', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd32ad1f1-4f5d-4674-8664-5316a5ad7324'	System	02 Sep 2020 23:54:54
User entered 'Yes (Y)'	System	02 Sep 2020 23:54:54

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:54:42', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd32ad1f1-4f5d-4674-8664-5316a5ad7324'	System	02 Sep 2020 23:54:54
User entered '98.3'	System	02 Sep 2020 23:54:54

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:54:45', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd32ad1f1-4f5d-4674-8664-5316a5ad7324'	System	02 Sep 2020 23:54:54
User entered 'No (N)'	System	02 Sep 2020 23:54:54

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:54:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd32ad1f1-4f5d-4674-8664-5316a5ad7324'	System	02 Sep 2020 23:54:54
User entered '02 Sep 2020 18:54'	System	02 Sep 2020 23:54:54

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 15:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 2'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:38:32', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4bcf3dfd-2620-4815-99ce-048aac0cc4c9'	System	04 Sep 2020 08:38:58
User entered 'Yes (Y)'	System	04 Sep 2020 08:38:58

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:38:48', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4bcf3dfd-2620-4815-99ce-048aac0cc4c9'	System	04 Sep 2020 08:38:58
User entered '98.4'	System	04 Sep 2020 08:38:58

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:38:53', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4bcf3dfd-2620-4815-99ce-048aac0cc4c9'	System	04 Sep 2020 08:38:58
User entered 'No (N)'	System	04 Sep 2020 08:38:58

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:38:57', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4bcf3dfd-2620-4815-99ce-048aac0cc4c9'	System	04 Sep 2020 08:38:58
User entered '04 Sep 2020 03:38'	System	04 Sep 2020 08:38:58

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 3'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5328eec5-bf5c-4120-b6ec-4ec0e151d463'	System	04 Sep 2020 17:44:49
User entered 'Yes (Y)'	System	04 Sep 2020 17:44:49

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:40', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5328eec5-bf5c-4120-b6ec-4ec0e151d463'	System	04 Sep 2020 17:44:49
User entered '98.6'	System	04 Sep 2020 17:44:49

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:43', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5328eec5-bf5c-4120-b6ec-4ec0e151d463'	System	04 Sep 2020 17:44:49
User entered 'No (N)'	System	04 Sep 2020 17:44:49

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:46', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5328eec5-bf5c-4120-b6ec-4ec0e151d463'	System	04 Sep 2020 17:44:49
User entered '04 Sep 2020 12:44'	System	04 Sep 2020 17:44:49

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 4'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:06:55', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fd45af09-ba05-499e-8dc5-7522adbe8863'	System	05 Sep 2020 21:07:07
User entered 'Yes (Y)'	System	05 Sep 2020 21:07:07

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fd45af09-ba05-499e-8dc5-7522adbe8863'	System	05 Sep 2020 21:07:07
User entered '98.2'	System	05 Sep 2020 21:07:07

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fd45af09-ba05-499e-8dc5-7522adbe8863'	System	05 Sep 2020 21:07:07
User entered 'No (N)'	System	05 Sep 2020 21:07:07

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:07', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fd45af09-ba05-499e-8dc5-7522adbe8863'	System	05 Sep 2020 21:07:07
User entered '05 Sep 2020 17:07'	System	05 Sep 2020 21:07:07

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 5'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:05:44', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c882ea4c-0d03-43b3-901e-a6f8cac5b474'	System	06 Sep 2020 16:06:03
User entered 'Yes (Y)'	System	06 Sep 2020 16:06:03

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:05:50', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c882ea4c-0d03-43b3-901e-a6f8cac5b474'	System	06 Sep 2020 16:06:03
User entered '97.6'	System	06 Sep 2020 16:06:03

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:05:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c882ea4c-0d03-43b3-901e-a6f8cac5b474'	System	06 Sep 2020 16:06:03
User entered 'No (N)'	System	06 Sep 2020 16:06:03

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:05:56', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c882ea4c-0d03-43b3-901e-a6f8cac5b474'	System	06 Sep 2020 16:06:03
User entered '06 Sep 2020 12:05'	System	06 Sep 2020 16:06:03

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 6'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:24:36', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c216bb03-c9ba-4115-b65b-57739c182982'	System	07 Sep 2020 16:24:55
User entered 'Yes (Y)'	System	07 Sep 2020 16:24:55

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:24:42', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c216bb03-c9ba-4115-b65b-57739c182982'	System	07 Sep 2020 16:24:55
User entered '97.9'	System	07 Sep 2020 16:24:55

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:24:47', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c216bb03-c9ba-4115-b65b-57739c182982'	System	07 Sep 2020 16:24:55
User entered 'No (N)'	System	07 Sep 2020 16:24:55

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:24:49', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c216bb03-c9ba-4115-b65b-57739c182982'	System	07 Sep 2020 16:24:55
User entered '07 Sep 2020 12:24'	System	07 Sep 2020 16:24:55

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 7'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:11:37', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5fb267d8-a347-49d3-a77e-82e21eb96e6d'	System	08 Sep 2020 18:11:53
User entered 'Yes (Y)'	System	08 Sep 2020 18:11:53

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:11:43', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5fb267d8-a347-49d3-a77e-82e21eb96e6d'	System	08 Sep 2020 18:11:53
User entered '98.4'	System	08 Sep 2020 18:11:53

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:11:45', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5fb267d8-a347-49d3-a77e-82e21eb96e6d'	System	08 Sep 2020 18:11:53
User entered 'No (N)'	System	08 Sep 2020 18:11:53

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:11:50', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5fb267d8-a347-49d3-a77e-82e21eb96e6d'	System	08 Sep 2020 18:11:53
User entered '08 Sep 2020 14:11'	System	08 Sep 2020 18:11:53

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:36', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '04cf10f8-28b5-45bd-826b-96bdc309a4fe'	System	02 Sep 2020 17:57:50
User entered 'None (1)'	System	02 Sep 2020 17:57:50

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:39', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '04cf10f8-28b5-45bd-826b-96bdc309a4fe'	System	02 Sep 2020 17:57:50
User entered 'No (N)'	System	02 Sep 2020 17:57:50

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:41', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '04cf10f8-28b5-45bd-826b-96bdc309a4fe'	System	02 Sep 2020 17:57:50
User entered 'No (N)'	System	02 Sep 2020 17:57:50

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:45', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '04cf10f8-28b5-45bd-826b-96bdc309a4fe'	System	02 Sep 2020 17:57:50
User entered 'None (1)'	System	02 Sep 2020 17:57:50

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:48', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '04cf10f8-28b5-45bd-826b-96bdc309a4fe'	System	02 Sep 2020 17:57:50
User entered '02 Sep 2020 12:57'	System	02 Sep 2020 17:57:50

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 12:34'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 15:04'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9481b5b2-9619-4f0f-8b26-5bc883329b71'	System	02 Sep 2020 23:55:34
User entered 'None (1)'	System	02 Sep 2020 23:55:34

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9481b5b2-9619-4f0f-8b26-5bc883329b71'	System	02 Sep 2020 23:55:34
User entered 'No (N)'	System	02 Sep 2020 23:55:34

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9481b5b2-9619-4f0f-8b26-5bc883329b71'	System	02 Sep 2020 23:55:34
User entered 'No (N)'	System	02 Sep 2020 23:55:34

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:26', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9481b5b2-9619-4f0f-8b26-5bc883329b71'	System	02 Sep 2020 23:55:34
User entered 'None (1)'	System	02 Sep 2020 23:55:34

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9481b5b2-9619-4f0f-8b26-5bc883329b71'	System	02 Sep 2020 23:55:34
User entered '02 Sep 2020 18:55'	System	02 Sep 2020 23:55:34

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 15:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 2'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:02', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5890cb53-0cc6-4893-bbdf-d9c94ba5eb3a'	System	04 Sep 2020 08:39:19
User entered 'None (1)'	System	04 Sep 2020 08:39:19

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5890cb53-0cc6-4893-bbdf-d9c94ba5eb3a'	System	04 Sep 2020 08:39:19
User entered 'No (N)'	System	04 Sep 2020 08:39:19

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:10', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5890cb53-0cc6-4893-bbdf-d9c94ba5eb3a'	System	04 Sep 2020 08:39:19
User entered 'No (N)'	System	04 Sep 2020 08:39:19

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:14', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5890cb53-0cc6-4893-bbdf-d9c94ba5eb3a'	System	04 Sep 2020 08:39:19
User entered 'None (1)'	System	04 Sep 2020 08:39:19

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5890cb53-0cc6-4893-bbdf-d9c94ba5eb3a'	System	04 Sep 2020 08:39:19
User entered '04 Sep 2020 03:39'	System	04 Sep 2020 08:39:19

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 3'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:50', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0001889d-469b-4983-9dcf-05b11ec9c6ea'	System	04 Sep 2020 17:45:04
User entered 'None (1)'	System	04 Sep 2020 17:45:04

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:53', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0001889d-469b-4983-9dcf-05b11ec9c6ea'	System	04 Sep 2020 17:45:04
User entered 'No (N)'	System	04 Sep 2020 17:45:04

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:55', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0001889d-469b-4983-9dcf-05b11ec9c6ea'	System	04 Sep 2020 17:45:04
User entered 'No (N)'	System	04 Sep 2020 17:45:04

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:57', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0001889d-469b-4983-9dcf-05b11ec9c6ea'	System	04 Sep 2020 17:45:04
User entered 'None (1)'	System	04 Sep 2020 17:45:04

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:44:59', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0001889d-469b-4983-9dcf-05b11ec9c6ea'	System	04 Sep 2020 17:45:04
User entered '04 Sep 2020 12:44'	System	04 Sep 2020 17:45:04

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 4'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:11', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ced4cae7-e83c-497e-8206-08a7fdea67ea'	System	05 Sep 2020 21:07:20
User entered 'None (1)'	System	05 Sep 2020 21:07:20

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:13', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ced4cae7-e83c-497e-8206-08a7fdea67ea'	System	05 Sep 2020 21:07:20
User entered 'No (N)'	System	05 Sep 2020 21:07:20

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:15', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ced4cae7-e83c-497e-8206-08a7fdea67ea'	System	05 Sep 2020 21:07:20
User entered 'No (N)'	System	05 Sep 2020 21:07:20

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ced4cae7-e83c-497e-8206-08a7fdea67ea'	System	05 Sep 2020 21:07:20
User entered 'None (1)'	System	05 Sep 2020 21:07:20

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:20', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ced4cae7-e83c-497e-8206-08a7fdea67ea'	System	05 Sep 2020 21:07:20
User entered '05 Sep 2020 17:07'	System	05 Sep 2020 21:07:20

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 5'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2810af1d-24b1-421b-a6ed-289c13d0d561'	System	06 Sep 2020 16:06:17
User entered 'None (1)'	System	06 Sep 2020 16:06:17

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2810af1d-24b1-421b-a6ed-289c13d0d561'	System	06 Sep 2020 16:06:17
User entered 'No (N)'	System	06 Sep 2020 16:06:17

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:08', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2810af1d-24b1-421b-a6ed-289c13d0d561'	System	06 Sep 2020 16:06:17
User entered 'No (N)'	System	06 Sep 2020 16:06:17

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:10', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2810af1d-24b1-421b-a6ed-289c13d0d561'	System	06 Sep 2020 16:06:17
User entered 'None (1)'	System	06 Sep 2020 16:06:17

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:13', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2810af1d-24b1-421b-a6ed-289c13d0d561'	System	06 Sep 2020 16:06:17
User entered '06 Sep 2020 12:06'	System	06 Sep 2020 16:06:17

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 6'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:24:59', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caa5d3a7-5c25-4dfc-b700-bacad14b added5'	System	07 Sep 2020 16:25:16
User entered 'None (1)'	System	07 Sep 2020 16:25:16

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caa5d3a7-5c25-4dfc-b700-bacad14bbdd5'	System	07 Sep 2020 16:25:16
User entered 'No (N)'	System	07 Sep 2020 16:25:16

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caa5d3a7-5c25-4dfc-b700-bacad14bbdd5'	System	07 Sep 2020 16:25:16
User entered 'No (N)'	System	07 Sep 2020 16:25:16

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:07', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caa5d3a7-5c25-4dfc-b700-bacad14b added5'	System	07 Sep 2020 16:25:16
User entered 'None (1)'	System	07 Sep 2020 16:25:16

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caa5d3a7-5c25-4dfc-b700-bacad14b added5'	System	07 Sep 2020 16:25:16
User entered '07 Sep 2020 12:25'	System	07 Sep 2020 16:25:16

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 7'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:11:57', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4eb6b184-65d7-40a5-a695-7e29aa9f490b'	System	08 Sep 2020 18:12:10
User entered 'None (1)'	System	08 Sep 2020 18:12:10

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:11:59', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4eb6b184-65d7-40a5-a695-7e29aa9f490b'	System	08 Sep 2020 18:12:10
User entered 'No (N)'	System	08 Sep 2020 18:12:10

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4eb6b184-65d7-40a5-a695-7e29aa9f490b'	System	08 Sep 2020 18:12:10
User entered 'No (N)'	System	08 Sep 2020 18:12:10

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4eb6b184-65d7-40a5-a695-7e29aa9f490b'	System	08 Sep 2020 18:12:10
User entered 'None (1)'	System	08 Sep 2020 18:12:10

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4eb6b184-65d7-40a5-a695-7e29aa9f490b'	System	08 Sep 2020 18:12:10
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:12:10

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:53', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered 'None (0)'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:56', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered 'None (0)'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:57:58', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered 'None (0)'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:58:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered 'None (0)'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:58:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered 'None (0)'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:58:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered 'None (0)'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:58:09', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered 'No (N)'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T12:58:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f1805f7b-9423-4fbb-8202-99a938d3a47f'	System	02 Sep 2020 17:58:14
User entered '02 Sep 2020 12:58'	System	02 Sep 2020 17:58:14

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 12:34'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 15:04'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:40', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered 'None (0)'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:44', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered 'None (0)'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:49', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered 'None (0)'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:54', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered 'None (0)'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:57', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered 'None (0)'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:55:59', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered 'None (0)'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:56:07', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered 'No (N)'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-02T18:56:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '61485073-75a9-4577-9681-a4998ea237bf'	System	02 Sep 2020 23:56:16
User entered '02 Sep 2020 18:56'	System	02 Sep 2020 23:56:16

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Sep 2020 15:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 2'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:21', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered 'None (0)'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:26', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered 'None (0)'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:29', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered 'None (0)'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:31', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered 'None (0)'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:35', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered 'None (0)'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:37', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered 'None (0)'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:42', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered 'No (N)'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T03:39:47', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a09dd549-1991-45d6-97c9-cac9dfeab7d1'	System	04 Sep 2020 08:39:50
User entered '04 Sep 2020 03:39'	System	04 Sep 2020 08:39:50

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 3'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered 'None (0)'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered 'None (0)'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:07', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered 'None (0)'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:09', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered 'None (0)'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered 'None (0)'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:14', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered 'None (0)'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered 'No (N)'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-04T12:45:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fed7ac9c-7d88-49e6-a54b-7b13998e5a98'	System	04 Sep 2020 17:45:23
User entered '04 Sep 2020 12:45'	System	04 Sep 2020 17:45:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 4'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:23', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered 'None (0)'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:25', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered 'None (0)'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:27', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered 'None (0)'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered 'None (0)'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:32', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered 'None (0)'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:33', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered 'None (0)'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:38', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered 'No (N)'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-05T17:07:41', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3888b539-cea6-4b03-add9-b07a55c1b3c2'	System	05 Sep 2020 21:07:41
User entered '05 Sep 2020 17:07'	System	05 Sep 2020 21:07:41

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 5'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered 'None (0)'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:18', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered 'None (0)'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:21', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered 'None (0)'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:23', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered 'None (0)'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:25', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered 'None (0)'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:27', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered 'None (0)'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:29', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered 'No (N)'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-06T12:06:33', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd0b8af47-6e8d-4237-9ae4-5144436f11c6'	System	06 Sep 2020 16:06:35
User entered '06 Sep 2020 12:06'	System	06 Sep 2020 16:06:35

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 6'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:26', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered 'None (0)'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered 'None (0)'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:32', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered 'None (0)'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:35', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered 'None (0)'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:38', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered 'None (0)'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:41', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered 'None (0)'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:44', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered 'No (N)'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-07T12:25:49', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '37712168-1b3d-4d38-931a-047f266ff302'	System	07 Sep 2020 16:25:54
User entered '07 Sep 2020 12:25'	System	07 Sep 2020 16:25:54

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 7'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:08', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered 'None (0)'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:09', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered 'None (0)'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:10', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered 'None (0)'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:11', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered 'None (0)'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:13', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered 'None (0)'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:15', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered 'None (0)'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:18', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered 'No (N)'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-08T14:12:20', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a3d2a2c9-7939-4fa9-8927-d3c1fe3b98f9'	System	08 Sep 2020 18:12:23
User entered '08 Sep 2020 14:12'	System	08 Sep 2020 18:12:23

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:17:39

US3912076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:55:01

US3912076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:55:01

US3912076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 21:55:01

US3912076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:55:01

US3912076

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	16 Sep 2020 19:46:36

US3912076

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	16 Sep 2020 19:46:36

US3912076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	16 Sep 2020 19:46:54

US3912076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '16 Sep 2020'	(b) (4) Monique Gawlik (b) (4)	16 Sep 2020 19:46:54

US3912076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	16 Sep 2020 19:46:54

US3912076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Monique Gawlik (b) (4)	16 Sep 2020 19:46:54

US3912076

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	16 Sep 2020 19:47:03

US3912076

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	16 Sep 2020 19:47:03

US3912076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Amy Collins (b) (4)	23 Sep 2020 21:18:44

US3912076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '23 Sep 2020'	Amy Collins (b) (4)	23 Sep 2020 21:18:44

US3912076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	23 Sep 2020 21:18:44

US3912076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Amy Collins (b) (4) (b) (4)	23 Sep 2020 21:18:44

US3912076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Amy Collins (b) (4)	23 Sep 2020 21:19:13

US3912076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	23 Sep 2020 21:19:13

US3912076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	30 Sep 2020 16:05:27

US3912076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '30 Sep 2020'	Tina Rountree (b) (4)	30 Sep 2020 16:05:27

US3912076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Tina Rountree (b) (4)	08 Oct 2020 15:32:40
User entered 'Home (Home)'	(b) (4)	
	Tina Rountree (b) (4)	30 Sep 2020 16:05:27
	(b) (4)	

US3912076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'VISIT2'	System	30 Sep 2020 16:05:27

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User accepted default value 'Pre-Dose (PREDOSE)'	Tina Rountree (b) (4) (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '30 Sep 2020'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '09:53'	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered '30 Sep 2020 09:53'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.9' C	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Oral (Oral)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '100'	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'bpm'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '16'	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'breaths/min'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '112'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'mmHg'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '75'	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'mmHg'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User accepted default value 'Post-Dose (POSTDOSE)'	Tina Rountree (b) (4) (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '30 Sep 2020'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '11:41'	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered '30 Sep 2020 11:41'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.9' C	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Oral (Oral)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '79'	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'bpm'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '14'	Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'breaths/min'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '108'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'mmHg'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '67'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'mmHg'	System	30 Sep 2020 16:47:21

US3912076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:35:51

US3912076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '30 Sep 2020'	Tina Rountree (b) (4)	30 Sep 2020 16:35:51

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '30 Sep 2020'	Tina Rountree (b) (4)	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '11:00'	Tina Rountree (b) (4)	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered '30 Sep 2020 11:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'ONCE'	System	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 16:04:19

US3912076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:06:17

US3912076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '30 Sep 2020'	Tina Rountree (b) (4)	30 Sep 2020 16:06:17

US3912076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '10:32'	Tina Rountree (b) (4)	30 Sep 2020 16:06:17

US3912076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered '30 Sep 2020 10:32'	System	30 Sep 2020 16:06:17

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:22:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '30 Sep 2020'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tina Rountree (b) (4) (b) (4)	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '10:36'	Tina Rountree (b) (4)	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered '30 Sep 2020 10:36'	System	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tina Rountree (b) (4) (b) (4)	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered empty.	System	30 Sep 2020 16:06:57

US3912076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	30 Sep 2020 16:36:00

US3912076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'I'	System	30 Sep 2020 16:36:00

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a7b82a90-6d8b-4be9-92cc-5dfc1b745d51'	System	30 Sep 2020 16:43:16
User entered 'Yes (Y)'	System	30 Sep 2020 16:43:16

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a7b82a90-6d8b-4be9-92cc-5dfc1b745d51'	System	30 Sep 2020 16:43:16
User entered '98.5'	System	30 Sep 2020 16:43:16

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:09', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a7b82a90-6d8b-4be9-92cc-5dfc1b745d51'	System	30 Sep 2020 16:43:16
User entered 'No (N)'	System	30 Sep 2020 16:43:16

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a7b82a90-6d8b-4be9-92cc-5dfc1b745d51'	System	30 Sep 2020 16:43:16
User entered '30 Sep 2020 11:43'	System	30 Sep 2020 16:43:16

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 11:20'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 13:50'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:15:35', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5b7fcb06-c5b2-4126-b5e3-925998e0a611'	System	30 Sep 2020 20:16:08
User entered 'Yes (Y)'	System	30 Sep 2020 20:16:08

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:15:41', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5b7fcb06-c5b2-4126-b5e3-925998e0a611'	System	30 Sep 2020 20:16:08
User entered '98.1'	System	30 Sep 2020 20:16:08

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:15:44', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5b7fcb06-c5b2-4126-b5e3-925998e0a611'	System	30 Sep 2020 20:16:08
User entered 'No (N)'	System	30 Sep 2020 20:16:08

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:15:47', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5b7fcb06-c5b2-4126-b5e3-925998e0a611'	System	30 Sep 2020 20:16:08
User entered '30 Sep 2020 15:15'	System	30 Sep 2020 20:16:08

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 14:45'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 2'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'eebdbd15-05d8-4b4a-86f6-f2c8f70ef7f2'	System	01 Oct 2020 23:44:14
User entered 'Yes (Y)'	System	01 Oct 2020 23:44:14

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'eebdbd15-05d8-4b4a-86f6-f2c8f70ef7f2'	System	01 Oct 2020 23:44:14
User entered '98.8'	System	01 Oct 2020 23:44:14

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:09', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'eebdbd15-05d8-4b4a-86f6-f2c8f70ef7f2'	System	01 Oct 2020 23:44:14
User entered 'No (N)'	System	01 Oct 2020 23:44:14

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'eebdbd15-05d8-4b4a-86f6-f2c8f70ef7f2'	System	01 Oct 2020 23:44:14
User entered '01 Oct 2020 18:44'	System	01 Oct 2020 23:44:14

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 3'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:25', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '780c93cf-93d3-4ef5-9c41-a1a57f403187'	System	02 Oct 2020 18:01:40
User entered 'Yes (Y)'	System	02 Oct 2020 18:01:40

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:29', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '780c93cf-93d3-4ef5-9c41-a1a57f403187'	System	02 Oct 2020 18:01:40
User entered '98.4'	System	02 Oct 2020 18:01:40

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:31', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '780c93cf-93d3-4ef5-9c41-a1a57f403187'	System	02 Oct 2020 18:01:40
User entered 'No (N)'	System	02 Oct 2020 18:01:40

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '780c93cf-93d3-4ef5-9c41-a1a57f403187'	System	02 Oct 2020 18:01:40
User entered '02 Oct 2020 13:01'	System	02 Oct 2020 18:01:40

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 4'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:14', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dadf8382-d74d-43bc-ba78-a8b7d2e1ba4d'	System	03 Oct 2020 22:49:26
User entered 'Yes (Y)'	System	03 Oct 2020 22:49:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dadf8382-d74d-43bc-ba78-a8b7d2e1ba4d'	System	03 Oct 2020 22:49:26
User entered '98.3'	System	03 Oct 2020 22:49:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:22', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dadf8382-d74d-43bc-ba78-a8b7d2e1ba4d'	System	03 Oct 2020 22:49:26
User entered 'No (N)'	System	03 Oct 2020 22:49:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:24', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dadf8382-d74d-43bc-ba78-a8b7d2e1ba4d'	System	03 Oct 2020 22:49:26
User entered '03 Oct 2020 17:49'	System	03 Oct 2020 22:49:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 5'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:11:43', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd69bad3a-6e94-4283-868c-1420648d48ca'	System	04 Oct 2020 18:11:58
User entered 'Yes (Y)'	System	04 Oct 2020 18:11:58

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:11:47', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd69bad3a-6e94-4283-868c-1420648d48ca'	System	04 Oct 2020 18:11:58
User entered '98.3'	System	04 Oct 2020 18:11:58

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:11:49', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd69bad3a-6e94-4283-868c-1420648d48ca'	System	04 Oct 2020 18:11:58
User entered 'No (N)'	System	04 Oct 2020 18:11:58

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:11:55', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd69bad3a-6e94-4283-868c-1420648d48ca'	System	04 Oct 2020 18:11:58
User entered '04 Oct 2020 13:11'	System	04 Oct 2020 18:11:58

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 6'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 7'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:49:55', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '91449c4f-5963-4bb1-bf2d-ac49fbf4561b'	System	07 Oct 2020 11:50:09
User entered 'Yes (Y)'	System	07 Oct 2020 11:50:09

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '91449c4f-5963-4bb1-bf2d-ac49fbf4561b'	System	07 Oct 2020 11:50:09
User entered '98.1'	System	07 Oct 2020 11:50:09

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '91449c4f-5963-4bb1-bf2d-ac49fbf4561b'	System	07 Oct 2020 11:50:09
User entered 'No (N)'	System	07 Oct 2020 11:50:09

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '91449c4f-5963-4bb1-bf2d-ac49fbf4561b'	System	07 Oct 2020 11:50:09
User entered '07 Oct 2020 07:50'	System	07 Oct 2020 11:50:09

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:16', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0df2aa38-f67c-4a4e-9e44-1877dc922720'	System	30 Sep 2020 16:43:31
User entered 'None (1)'	System	30 Sep 2020 16:43:31

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:20', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0df2aa38-f67c-4a4e-9e44-1877dc922720'	System	30 Sep 2020 16:43:31
User entered 'No (N)'	System	30 Sep 2020 16:43:31

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:22', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0df2aa38-f67c-4a4e-9e44-1877dc922720'	System	30 Sep 2020 16:43:31
User entered 'No (N)'	System	30 Sep 2020 16:43:31

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:25', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0df2aa38-f67c-4a4e-9e44-1877dc922720'	System	30 Sep 2020 16:43:31
User entered 'None (1)'	System	30 Sep 2020 16:43:31

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:28', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0df2aa38-f67c-4a4e-9e44-1877dc922720'	System	30 Sep 2020 16:43:31
User entered '30 Sep 2020 11:43'	System	30 Sep 2020 16:43:31

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 11:20'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 13:50'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:15:53', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4d995951-3d84-482a-8737-aaf9fb1b9542'	System	30 Sep 2020 20:16:10
User entered 'None (1)'	System	30 Sep 2020 20:16:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:15:56', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4d995951-3d84-482a-8737-aaf9fb1b9542'	System	30 Sep 2020 20:16:10
User entered 'No (N)'	System	30 Sep 2020 20:16:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:15:59', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4d995951-3d84-482a-8737-aaf9fb1b9542'	System	30 Sep 2020 20:16:10
User entered 'No (N)'	System	30 Sep 2020 20:16:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:02', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4d995951-3d84-482a-8737-aaf9fb1b9542'	System	30 Sep 2020 20:16:10
User entered 'None (1)'	System	30 Sep 2020 20:16:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:07', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '4d995951-3d84-482a-8737-aaf9fb1b9542'	System	30 Sep 2020 20:16:10
User entered '30 Sep 2020 15:16'	System	30 Sep 2020 20:16:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 14:45'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 2'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '06b2fb06-f81f-47ed-b499-394a69d48723'	System	01 Oct 2020 23:44:32
User entered 'None (1)'	System	01 Oct 2020 23:44:32

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:22', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '06b2fb06-f81f-47ed-b499-394a69d48723'	System	01 Oct 2020 23:44:32
User entered 'No (N)'	System	01 Oct 2020 23:44:32

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:24', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '06b2fb06-f81f-47ed-b499-394a69d48723'	System	01 Oct 2020 23:44:32
User entered 'No (N)'	System	01 Oct 2020 23:44:32

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:26', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '06b2fb06-f81f-47ed-b499-394a69d48723'	System	01 Oct 2020 23:44:32
User entered 'None (1)'	System	01 Oct 2020 23:44:32

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:29', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '06b2fb06-f81f-47ed-b499-394a69d48723'	System	01 Oct 2020 23:44:32
User entered '01 Oct 2020 18:44'	System	01 Oct 2020 23:44:32

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 3'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:45', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ca69953b-cf51-4ad1-8c35-7f71c98b86d2'	System	02 Oct 2020 18:02:08
User entered 'None (1)'	System	02 Oct 2020 18:02:08

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:49', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ca69953b-cf51-4ad1-8c35-7f71c98b86d2'	System	02 Oct 2020 18:02:08
User entered 'No (N)'	System	02 Oct 2020 18:02:08

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:53', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ca69953b-cf51-4ad1-8c35-7f71c98b86d2'	System	02 Oct 2020 18:02:08
User entered 'No (N)'	System	02 Oct 2020 18:02:08

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:01:57', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ca69953b-cf51-4ad1-8c35-7f71c98b86d2'	System	02 Oct 2020 18:02:08
User entered 'None (1)'	System	02 Oct 2020 18:02:08

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ca69953b-cf51-4ad1-8c35-7f71c98b86d2'	System	02 Oct 2020 18:02:08
User entered '02 Oct 2020 13:02'	System	02 Oct 2020 18:02:08

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 4'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:28', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '995f2dc0-137e-4d0c-a0b7-e8b756216e8e'	System	03 Oct 2020 22:49:42
User entered 'None (1)'	System	03 Oct 2020 22:49:42

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '995f2dc0-137e-4d0c-a0b7-e8b756216e8e'	System	03 Oct 2020 22:49:42
User entered 'No (N)'	System	03 Oct 2020 22:49:42

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:32', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '995f2dc0-137e-4d0c-a0b7-e8b756216e8e'	System	03 Oct 2020 22:49:42
User entered 'No (N)'	System	03 Oct 2020 22:49:42

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:35', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '995f2dc0-137e-4d0c-a0b7-e8b756216e8e'	System	03 Oct 2020 22:49:42
User entered 'None (1)'	System	03 Oct 2020 22:49:42

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:38', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '995f2dc0-137e-4d0c-a0b7-e8b756216e8e'	System	03 Oct 2020 22:49:42
User entered '03 Oct 2020 17:49'	System	03 Oct 2020 22:49:42

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 5'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6a6a7246-83ab-45ad-80ad-24b521895068'	System	04 Oct 2020 18:12:10
User entered 'None (1)'	System	04 Oct 2020 18:12:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:02', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6a6a7246-83ab-45ad-80ad-24b521895068'	System	04 Oct 2020 18:12:10
User entered 'No (N)'	System	04 Oct 2020 18:12:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6a6a7246-83ab-45ad-80ad-24b521895068'	System	04 Oct 2020 18:12:10
User entered 'No (N)'	System	04 Oct 2020 18:12:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6a6a7246-83ab-45ad-80ad-24b521895068'	System	04 Oct 2020 18:12:10
User entered 'None (1)'	System	04 Oct 2020 18:12:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:08', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6a6a7246-83ab-45ad-80ad-24b521895068'	System	04 Oct 2020 18:12:10
User entered '04 Oct 2020 13:12'	System	04 Oct 2020 18:12:10

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 6'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 7'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:10', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '83139472-84ae-4fa4-8152-854f68a17d7a'	System	07 Oct 2020 11:50:21
User entered 'None (1)'	System	07 Oct 2020 11:50:21

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '83139472-84ae-4fa4-8152-854f68a17d7a'	System	07 Oct 2020 11:50:21
User entered 'No (N)'	System	07 Oct 2020 11:50:21

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:15', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '83139472-84ae-4fa4-8152-854f68a17d7a'	System	07 Oct 2020 11:50:21
User entered 'No (N)'	System	07 Oct 2020 11:50:21

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '83139472-84ae-4fa4-8152-854f68a17d7a'	System	07 Oct 2020 11:50:21
User entered 'None (1)'	System	07 Oct 2020 11:50:21

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:20', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '83139472-84ae-4fa4-8152-854f68a17d7a'	System	07 Oct 2020 11:50:21
User entered '07 Oct 2020 07:50'	System	07 Oct 2020 11:50:21

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:32', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered 'None (0)'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered 'None (0)'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:37', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered 'None (0)'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:40', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered 'None (0)'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:43', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered 'None (0)'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:45', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered 'None (0)'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:43:58', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered 'No (N)'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T11:44:01', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f2bffc88-db24-400d-9872-4f9098d16f6d'	System	30 Sep 2020 16:44:04
User entered '30 Sep 2020 11:44'	System	30 Sep 2020 16:44:04

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 11:20'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 13:50'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:11', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered 'None (0)'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered 'None (0)'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:21', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered 'None (0)'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:28', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered 'None (0)'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:31', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered 'None (0)'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:33', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered 'None (0)'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:38', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered 'No (N)'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-09-30T15:16:41', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'caffebf7-c6de-476d-b1b2-6aa6d523c4c5'	System	30 Sep 2020 20:16:43
User entered '30 Sep 2020 15:16'	System	30 Sep 2020 20:16:43

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '30 Sep 2020 14:45'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 2'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:33', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered 'None (0)'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:48', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered 'Some interference with activity (2)'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:44:55', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered 'No interference with activity (1)'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:45:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered 'None (0)'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:45:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered 'None (0)'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:45:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered 'None (0)'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:45:10', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered 'No (N)'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-01T18:45:13', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3d222f29-6912-47bf-883a-47eb176839f7'	System	01 Oct 2020 23:45:17
User entered '01 Oct 2020 18:45'	System	01 Oct 2020 23:45:17

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 3'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered 'None (0)'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:14', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered 'None (0)'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered 'None (0)'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:20', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered 'None (0)'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:23', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered 'None (0)'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:26', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered 'None (0)'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered 'No (N)'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-02T13:02:33', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'ab1a0014-3c06-4926-ba46-1c7d731d2c34'	System	02 Oct 2020 18:02:35
User entered '02 Oct 2020 13:02'	System	02 Oct 2020 18:02:35

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 4'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:43', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered 'None (0)'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:46', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered 'None (0)'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:47', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered 'None (0)'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:49', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered 'None (0)'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:51', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered 'None (0)'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:53', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered 'None (0)'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:56', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered 'No (N)'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-03T17:49:58', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '6741cb70-8a5b-47d3-b609-bee13b18cc53'	System	03 Oct 2020 22:50:00
User entered '03 Oct 2020 17:49'	System	03 Oct 2020 22:50:00

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 5'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered 'None (0)'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:13', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered 'None (0)'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:15', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered 'None (0)'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:16', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered 'None (0)'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:18', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered 'None (0)'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:20', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered 'None (0)'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:22', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered 'No (N)'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-04T13:12:24', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '642175a3-eea7-444b-af8c-778f0b9aaf64'	System	04 Oct 2020 18:12:26
User entered '04 Oct 2020 13:12'	System	04 Oct 2020 18:12:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 6'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	30 Sep 2020 16:04:19
User entered 'Day 7'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:23', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered 'None (0)'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:25', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered 'None (0)'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:27', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered 'None (0)'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:29', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered 'None (0)'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered 'None (0)'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:32', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered 'None (0)'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:35', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered 'No (N)'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-10-07T07:50:38', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '81562dff-d99f-4e9b-ad36-7300b3849ae9'	System	07 Oct 2020 11:50:42
User entered '07 Oct 2020 07:50'	System	07 Oct 2020 11:50:42

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:04:19

US3912076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:22:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:04:19

US3912076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	08 Oct 2020 15:30:22

US3912076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '8 Oct 2020'	Tina Rountree (b) (4)	08 Oct 2020 15:30:22

US3912076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tina Rountree (b) (4)	08 Oct 2020 15:30:22

US3912076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	08 Oct 2020 15:30:22

US3912076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	08 Oct 2020 15:30:28

US3912076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	08 Oct 2020 15:30:28

US3912076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Amy Collins (b) (4)	14 Oct 2020 19:52:10

US3912076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '14 Oct 2020'	Amy Collins (b) (4)	14 Oct 2020 19:52:10

US3912076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	14 Oct 2020 19:52:10

US3912076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Amy Collins (b) (4)	14 Oct 2020 19:52:10

US3912076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Amy Collins (b) (4)	14 Oct 2020 19:52:14

US3912076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	14 Oct 2020 19:52:14

US3912076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Mia Rountree (b) (4)	21 Oct 2020 20:17:35

US3912076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '21 Oct 2020'	Mia Rountree (b) (4)	21 Oct 2020 20:17:35

US3912076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	21 Oct 2020 20:17:35

US3912076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Mia Rountree (b) (4)	21 Oct 2020 20:17:35

US3912076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Mia Rountree (b) (4)	21 Oct 2020 20:17:40

US3912076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	21 Oct 2020 20:17:40

US3912076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	29 Oct 2020 15:15:55

US3912076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '28 Oct 2020'	(b) (4) Sandra Clancy (b) (4)	29 Oct 2020 15:15:55

US3912076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[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 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Clinic (Clinic)'	Sandra Clancy (b) (4)	29 Oct 2020 15:15:55

US3912076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'VISIT3'	System	29 Oct 2020 15:15:55

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '28 Oct 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '15:56'	Sandra Clancy (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered '28 Oct 2020 15:56'	System	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '97.4' F	Sandra Clancy (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Oral (Oral)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '81'	Sandra Clancy (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'bpm'	System	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '16'	Sandra Clancy (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'breaths/min'	System	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '117'	(b) (4) Sandra Clancy (b) (4) (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'mmHg'	System	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '74'	Sandra Clancy (b) (4)	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'mmHg'	System	29 Oct 2020 15:16:39

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40

US3912076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40

US3912076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	Sandra Clancy (b) (4)	29 Oct 2020 15:16:45

US3912076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Sandra Clancy (b) (4)	29 Oct 2020 15:16:45

US3912076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 28OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:27:10
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 28OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'Lab collected REQ # 1F619675382' (Site from DM).	Mia Rountree (b) (4)	09 Nov 2020 17:24:54
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 28OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 19:11:42
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	29 Oct 2020 15:17:04

US3912076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '28 Oct 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	29 Oct 2020 15:17:04

US3912076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '16:10'	Sandra Clancy (b) (4)	29 Oct 2020 15:17:04

US3912076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered '28 Oct 2020 16:10'	System	29 Oct 2020 15:17:04

US3912076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	29 Oct 2020 15:17:07

US3912076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:40
User entered 'I'	System	29 Oct 2020 15:17:07

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 64'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-02T03:00:06', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '975b37fe-0806-47af-94b6-6f707da227b0'	System	02 Nov 2020 09:00:21
User entered 'No (N)'	System	02 Nov 2020 09:00:21

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-02T03:00:10', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '975b37fe-0806-47af-94b6-6f707da227b0'	System	02 Nov 2020 09:00:21
User entered 'No (N)'	System	02 Nov 2020 09:00:21

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-02T03:00:14', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '975b37fe-0806-47af-94b6-6f707da227b0'	System	02 Nov 2020 09:00:21
User entered '02 Nov 2020 03:00:14'	System	02 Nov 2020 09:00:21

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 71'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-09T06:08:41', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a25e2458-78be-4370-aa59-220a3ad01819'	System	09 Nov 2020 11:08:54
User entered 'No (N)'	System	09 Nov 2020 11:08:54

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-09T06:08:46', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a25e2458-78be-4370-aa59-220a3ad01819'	System	09 Nov 2020 11:08:54
User entered 'No (N)'	System	09 Nov 2020 11:08:54

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-09T06:08:51', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'a25e2458-78be-4370-aa59-220a3ad01819'	System	09 Nov 2020 11:08:54
User entered '09 Nov 2020 06:08:51'	System	09 Nov 2020 11:08:54

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered 'Day 78'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-16T02:03:21', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '752f3eb8-7906-4afa-82d0-d981dd7c85a9'	System	16 Nov 2020 07:03:31
User entered 'No (N)'	System	16 Nov 2020 07:03:31

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-16T02:03:26', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '752f3eb8-7906-4afa-82d0-d981dd7c85a9'	System	16 Nov 2020 07:03:31
User entered 'No (N)'	System	16 Nov 2020 07:03:31

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-16T02:03:28', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '752f3eb8-7906-4afa-82d0-d981dd7c85a9'	System	16 Nov 2020 07:03:31
User entered '16 Nov 2020 02:03:28'	System	16 Nov 2020 07:03:31

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 17:17:39

US3912076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:48:26
Data entry locked.	System	02 Sep 2020 17:17:39
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 17:17:39

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2020-11-23T18:02:50', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered 'Yes (Y)'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2020-11-23T18:02:54', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered 'No (N)'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'the subject was contacted upon site receiving notification of diary entry. When reviewed with the subject, it was noted that she had not been reading the entire question and the responses that are noted here are incorrect. Source documentation is available to verify this response.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 05:42:01
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Sandra Clancy (b) (4)	21 Dec 2020 16:19:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	(b) (4), (b) (6)	19 Dec 2020 16:49:42
User entered 'Yes (Y)'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be' User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '1'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be' User entered '1'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be' User entered '1'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '1'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be' User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be' User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered '0'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:37', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:43', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered 'Yes (Y)'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:47', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be'	System	24 Nov 2020 00:04:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-23T18:03:53', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '8868bb15-2fbd-4510-a197-5742d3dcb1be' User entered '23 Nov 2020 18:03:53'	System	24 Nov 2020 00:04:04

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2020-11-27T08:17:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered 'Yes (Y)'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2020-11-27T08:17:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered 'No (N)'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered 'Yes (Y)'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604' User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '1'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604' User entered '1'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '1'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '1'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '1'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '1'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '0'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:38', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:44', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered 'No (N)'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-11-27T08:17:48', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'd8e78813-ce1d-4d6c-9767-181bfd17a604'	System	27 Nov 2020 14:17:57
User entered '27 Nov 2020 08:17:48'	System	27 Nov 2020 14:17:57

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2020-12-04T02:26:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered 'Yes (Y)'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2020-12-04T02:26:17', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered 'Yes (Y)'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:20', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:33', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered 'Yes (Y)'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '1'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd' User entered '0'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:26:55', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:27:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered 'Yes (Y)'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:27:07', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-04T02:27:11', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '58568146-1a6d-40ed-b012-7d1263deb6cd'	System	04 Dec 2020 08:27:21
User entered '04 Dec 2020 02:27:11'	System	04 Dec 2020 08:27:21

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2020-12-11T03:07:23', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'bd3cf43e-fc1f-40e5-839f-3517a84833e2'	System	11 Dec 2020 08:07:33
User entered 'No (N)'	System	11 Dec 2020 08:07:33

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2020-12-11T03:07:28', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'bd3cf43e-fc1f-40e5-839f-3517a84833e2'	System	11 Dec 2020 08:07:33
User entered 'No (N)'	System	11 Dec 2020 08:07:33

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-11T03:07:32', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'bd3cf43e-fc1f-40e5-839f-3517a84833e2'	System	11 Dec 2020 08:07:33
User entered '11 Dec 2020 03:07:32'	System	11 Dec 2020 08:07:33

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2020-12-21T08:00:51', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f5223916-21fd-4b8f-a061-01214efbf4d0'	System	21 Dec 2020 14:01:01
User entered 'No (N)'	System	21 Dec 2020 14:01:01

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2020-12-21T08:00:55', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f5223916-21fd-4b8f-a061-01214efbf4d0'	System	21 Dec 2020 14:01:01
User entered 'No (N)'	System	21 Dec 2020 14:01:01

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-21T08:00:58', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f5223916-21fd-4b8f-a061-01214efbf4d0'	System	21 Dec 2020 14:01:01
User entered '21 Dec 2020 08:00:58'	System	21 Dec 2020 14:01:01

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2020-12-25T16:56:21', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c15259df-b4b6-4e71-9f13-17c676673620'	System	25 Dec 2020 22:56:31
User entered 'No (N)'	System	25 Dec 2020 22:56:31

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2020-12-25T16:56:23', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c15259df-b4b6-4e71-9f13-17c676673620'	System	25 Dec 2020 22:56:31
User entered 'No (N)'	System	25 Dec 2020 22:56:31

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2020-12-25T16:56:25', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'c15259df-b4b6-4e71-9f13-17c676673620' User entered '25 Dec 2020 16:56:25'	System	25 Dec 2020 22:56:31

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-01-01T14:08:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2b7bd7d8-0c6b-4e84-b53c-96956e393cff'	System	01 Jan 2021 20:08:13
User entered 'No (N)'	System	01 Jan 2021 20:08:13

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-01-01T14:08:07', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2b7bd7d8-0c6b-4e84-b53c-96956e393cff'	System	01 Jan 2021 20:08:13
User entered 'No (N)'	System	01 Jan 2021 20:08:13

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-01-01T14:08:11', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '2b7bd7d8-0c6b-4e84-b53c-96956e393cff'	System	01 Jan 2021 20:08:13
User entered '01 Jan 2021 14:08:11'	System	01 Jan 2021 20:08:13

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-01-08T17:35:31', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3b4bcaa7-a8d9-477b-8b45-61ce4c07c3f3'	System	08 Jan 2021 23:35:38
User entered 'No (N)'	System	08 Jan 2021 23:35:38

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-01-08T17:35:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3b4bcaa7-a8d9-477b-8b45-61ce4c07c3f3'	System	08 Jan 2021 23:35:38
User entered 'No (N)'	System	08 Jan 2021 23:35:38

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-01-08T17:35:37', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3b4bcaa7-a8d9-477b-8b45-61ce4c07c3f3'	System	08 Jan 2021 23:35:38
User entered '08 Jan 2021 17:35:37'	System	08 Jan 2021 23:35:38

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-01-15T05:18:51', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fa8cf48b-f136-4f24-8b42-6a536327e5e6'	System	15 Jan 2021 11:19:16
User entered 'No (N)'	System	15 Jan 2021 11:19:16

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-01-15T05:19:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fa8cf48b-f136-4f24-8b42-6a536327e5e6'	System	15 Jan 2021 11:19:16
User entered 'No (N)'	System	15 Jan 2021 11:19:16

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-01-15T05:19:09', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fa8cf48b-f136-4f24-8b42-6a536327e5e6'	System	15 Jan 2021 11:19:16
User entered '15 Jan 2021 05:19:09'	System	15 Jan 2021 11:19:16

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-01-22T02:11:26', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3e4c4e49-d028-440c-83d3-7b841c3f997a'	System	22 Jan 2021 08:11:34
User entered 'No (N)'	System	22 Jan 2021 08:11:34

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-01-22T02:11:30', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3e4c4e49-d028-440c-83d3-7b841c3f997a'	System	22 Jan 2021 08:11:34
User entered 'No (N)'	System	22 Jan 2021 08:11:34

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-01-22T02:11:33', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3e4c4e49-d028-440c-83d3-7b841c3f997a' User entered '22 Jan 2021 02:11:33'	System	22 Jan 2021 08:11:34

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-02-01T08:48:50', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '7b8aec38-9771-439c-b0aa-f42bd8c1eb1a'	System	01 Feb 2021 14:49:36
User entered 'Yes (Y)'	System	01 Feb 2021 14:49:36

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-02-01T08:48:57', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '7b8aec38-9771-439c-b0aa-f42bd8c1eb1a'	System	01 Feb 2021 14:49:36
User entered 'No (N)'	System	01 Feb 2021 14:49:36

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-01T08:49:03', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '7b8aec38-9771-439c-b0aa-f42bd8c1eb1a'	System	01 Feb 2021 14:49:36
User entered 'No (N)'	System	01 Feb 2021 14:49:36

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-01T08:49:11', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '7b8aec38-9771-439c-b0aa-f42bd8c1eb1a'	System	01 Feb 2021 14:49:36
User entered 'Yes (Y)'	System	01 Feb 2021 14:49:36

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-01T08:49:19', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '7b8aec38-9771-439c-b0aa-f42bd8c1eb1a'	System	01 Feb 2021 14:49:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 14:49:36

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-01T08:49:27', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '7b8aec38-9771-439c-b0aa-f42bd8c1eb1a'	System	01 Feb 2021 14:49:36
User entered '01 Feb 2021 08:49:27'	System	01 Feb 2021 14:49:36

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-02-05T04:42:05', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f9855db6-55e0-4736-9226-10eb6c37869d'	System	05 Feb 2021 10:42:18
User entered 'No (N)'	System	05 Feb 2021 10:42:18

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-02-05T04:42:09', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f9855db6-55e0-4736-9226-10eb6c37869d'	System	05 Feb 2021 10:42:18
User entered 'No (N)'	System	05 Feb 2021 10:42:18

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-05T04:42:12', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'f9855db6-55e0-4736-9226-10eb6c37869d'	System	05 Feb 2021 10:42:18
User entered '05 Feb 2021 04:42:12'	System	05 Feb 2021 10:42:18

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-02-14T12:19:57', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dbef5937-f647-4934-a80c-05e274d1f98f'	System	14 Feb 2021 18:20:22
User entered 'Yes (Y)'	System	14 Feb 2021 18:20:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-02-14T12:19:52', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dbef5937-f647-4934-a80c-05e274d1f98f'	System	14 Feb 2021 18:20:22
User entered 'No (N)'	System	14 Feb 2021 18:20:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-14T12:19:51', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dbef5937-f647-4934-a80c-05e274d1f98f'	System	14 Feb 2021 18:20:22
User entered 'No (N)'	System	14 Feb 2021 18:20:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-14T12:20:04', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dbef5937-f647-4934-a80c-05e274d1f98f'	System	14 Feb 2021 18:20:22
User entered 'Yes (Y)'	System	14 Feb 2021 18:20:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-14T12:20:10', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dbef5937-f647-4934-a80c-05e274d1f98f'	System	14 Feb 2021 18:20:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 18:20:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-14T12:20:13', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'dbef5937-f647-4934-a80c-05e274d1f98f'	System	14 Feb 2021 18:20:22
User entered '14 Feb 2021 12:20:13'	System	14 Feb 2021 18:20:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-02-19T07:14:31', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5bba13fe-a01d-468e-aebb-dc22fe15b2b2'	System	19 Feb 2021 13:14:39
User entered 'No (N)'	System	19 Feb 2021 13:14:39

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-02-19T07:14:34', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5bba13fe-a01d-468e-aebb-dc22fe15b2b2'	System	19 Feb 2021 13:14:39
User entered 'No (N)'	System	19 Feb 2021 13:14:39

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-19T07:14:36', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '5bba13fe-a01d-468e-aebb-dc22fe15b2b2'	System	19 Feb 2021 13:14:39
User entered '19 Feb 2021 07:14:36'	System	19 Feb 2021 13:14:39

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-02-26T06:43:05-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '1a720afc-7dc1-4fda-b3d5-7e442ba250b5'	System	26 Feb 2021 12:43:15
User entered 'No (N)'	System	26 Feb 2021 12:43:15

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-02-26T06:43:08-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '1a720afc-7dc1-4fda-b3d5-7e442ba250b5'	System	26 Feb 2021 12:43:15
User entered 'No (N)'	System	26 Feb 2021 12:43:15

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-02-26T06:43:11-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '1a720afc-7dc1-4fda-b3d5-7e442ba250b5' User entered '26 Feb 2021 06:43:11'	System	26 Feb 2021 12:43:15
	System	26 Feb 2021 12:43:15

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-03-07T20:40:01-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'e435ec33-7127-4e03-859c-a1c5f8363d69'	System	08 Mar 2021 02:41:52
User entered 'No (N)'	System	08 Mar 2021 02:41:52

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-03-07T20:40:05-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'e435ec33-7127-4e03-859c-a1c5f8363d69'	System	08 Mar 2021 02:41:52
User entered 'No (N)'	System	08 Mar 2021 02:41:52

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-03-07T20:40:08-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'e435ec33-7127-4e03-859c-a1c5f8363d69'	System	08 Mar 2021 02:41:52
User entered '07 Mar 2021 20:40:08'	System	08 Mar 2021 02:41:52

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-03-12T07:16:44-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0a845c96-0c90-4228-8804-1b6fc0d005a0'	System	12 Mar 2021 13:16:52
User entered 'No (N)'	System	12 Mar 2021 13:16:52

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-03-12T07:16:47-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0a845c96-0c90-4228-8804-1b6fc0d005a0'	System	12 Mar 2021 13:16:52
User entered 'No (N)'	System	12 Mar 2021 13:16:52

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-03-12T07:16:50-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '0a845c96-0c90-4228-8804-1b6fc0d005a0'	System	12 Mar 2021 13:16:52
User entered '12 Mar 2021 07:16:50'	System	12 Mar 2021 13:16:52

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-03-20T12:45:05-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '07bffdf0-d8e0-4df3-9bdb-d46d68c69765'	System	20 Mar 2021 17:45:16
User entered 'No (N)'	System	20 Mar 2021 17:45:16

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-03-20T12:45:11-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '07bffdf0-d8e0-4df3-9bdb-d46d68c69765'	System	20 Mar 2021 17:45:16
User entered 'No (N)'	System	20 Mar 2021 17:45:16

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-03-20T12:45:13-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '07bffd0-d8e0-4df3-9bdb-d46d68c69765'	System	20 Mar 2021 17:45:16
User entered '20 Mar 2021 12:45:13'	System	20 Mar 2021 17:45:16

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-03-26T15:04:01-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '94e81c35-6425-4af9-8b0e-696824d7db8e' User entered 'No (N)'	System	26 Mar 2021 20:04:12
	System	26 Mar 2021 20:04:12

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-03-26T15:04:04-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '94e81c35-6425-4af9-8b0e-696824d7db8e'	System	26 Mar 2021 20:04:12
User entered 'No (N)'	System	26 Mar 2021 20:04:12

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-03-26T15:04:07-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '94e81c35-6425-4af9-8b0e-696824d7db8e' User entered '26 Mar 2021 15:04:07'	System	26 Mar 2021 20:04:12
	System	26 Mar 2021 20:04:12

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-04-02T00:24:47-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9a4d407f-df90-4416-8d53-4c6842ba93fa' User entered 'No (N)'	System	02 Apr 2021 05:24:59
	System	02 Apr 2021 05:24:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-04-02T00:24:51-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9a4d407f-df90-4416-8d53-4c6842ba93fa' User entered 'No (N)'	System	02 Apr 2021 05:24:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-04-02T00:24:54-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '9a4d407f-df90-4416-8d53-4c6842ba93fa' User entered '02 Apr 2021 00:24:54'	System	02 Apr 2021 05:24:59
	System	02 Apr 2021 05:24:59

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-04-09T12:55:56-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3632f607-fe24-48be-b1f4-c5d309bcf12a' User entered 'No (N)'	System	09 Apr 2021 17:56:08
	System	09 Apr 2021 17:56:08

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-04-09T12:55:58-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3632f607-fe24-48be-b1f4-c5d309bcf12a'	System	09 Apr 2021 17:56:08
User entered 'No (N)'	System	09 Apr 2021 17:56:08

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-04-09T12:56:01-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '3632f607-fe24-48be-b1f4-c5d309bcf12a'	System	09 Apr 2021 17:56:08
User entered '09 Apr 2021 12:56:01'	System	09 Apr 2021 17:56:08

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-04-19T11:18:44-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fa5863b7-0bb9-4fd9-87f5-224c68043719'	System	19 Apr 2021 16:18:53
User entered 'No (N)'	System	19 Apr 2021 16:18:53

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-04-19T11:18:47-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fa5863b7-0bb9-4fd9-87f5-224c68043719'	System	19 Apr 2021 16:18:53
User entered 'No (N)'	System	19 Apr 2021 16:18:53

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-04-19T11:18:49-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'fa5863b7-0bb9-4fd9-87f5-224c68043719' User entered '19 Apr 2021 11:18:49'	System	19 Apr 2021 16:18:53
	System	19 Apr 2021 16:18:53

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-04-27T10:46:30-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'cfb85ddf-144e-4880-a2c4-d9c4a2ed9937'	System	29 Apr 2021 03:34:48
User entered 'No (N)'	System	29 Apr 2021 03:34:48

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-04-27T10:46:31-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'cfb85ddf-144e-4880-a2c4-d9c4a2ed9937'	System	29 Apr 2021 03:34:48
User entered 'No (N)'	System	29 Apr 2021 03:34:48

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-04-27T10:46:34-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: 'cfb85ddf-144e-4880-a2c4-d9c4a2ed9937'	System	29 Apr 2021 03:34:48
User entered '27 Apr 2021 10:46:34'	System	29 Apr 2021 03:34:48

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you had 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 (db3232d966827864)', Time: '2021-04-30T00:16:40-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '001955c1-6f86-48ae-82d4-8d554f6983f6' User entered 'No (N)'	System	30 Apr 2021 05:16:50
	System	30 Apr 2021 05:16:50

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Have you been exposed to someone with known SARS-CoV-2 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 (db3232d966827864)', Time: '2021-04-30T00:16:42-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '001955c1-6f86-48ae-82d4-8d554f6983f6' User entered 'No (N)'	System	30 Apr 2021 05:16:50
	System	30 Apr 2021 05:16:50

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-04-30T00:16:45-05:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '001955c1-6f86-48ae-82d4-8d554f6983f6'	System	30 Apr 2021 05:16:50
User entered '30 Apr 2021 00:16:45'	System	30 Apr 2021 05:16:50

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:31:22

US3912076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:31:22
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:31:22

US3912076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:22:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:22:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-03-03T09:41:10-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '580d2a63-31bd-471a-980c-ae49205e8c75'	System	03 Mar 2021 15:41:16
User entered 'No (N)'	System	03 Mar 2021 15:41:16

US3912076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:22:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:22:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (db3232d966827864)', Time: '2021-03-03T09:41:13-06:00', User OID: 'PatientReportedOutcome (US3912076)', ODM File OID: '580d2a63-31bd-471a-980c-ae49205e8c75'	System	03 Mar 2021 15:41:16
User entered '03 Mar 2021 09:41:13'	System	03 Mar 2021 15:41:16

US3912076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Amy Collins (b) (4)	18 Dec 2020 22:20:43

US3912076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '23 Nov 2020'	Amy Collins (b) (4)	18 Dec 2020 22:20:43

US3912076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	18 Dec 2020 22:20:43

US3912076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Amy Collins (b) (4)	18 Dec 2020 22:20:43

US3912076

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Amy Collins (b) (4)	18 Dec 2020 22:20:51

US3912076

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:41:39
User entered 'I'	System	18 Dec 2020 22:20:51

US3912076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	29 Dec 2020 16:54:54

US3912076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '29 Dec 2020'	(b) (4) Monique Gawlik (b) (4)	29 Dec 2020 16:54:54

US3912076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	29 Dec 2020 16:54:54

US3912076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	(b) (4) Monique Gawlik (b) (4)	29 Dec 2020 16:54:54

US3912076

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	29 Dec 2020 16:55:02

US3912076

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered 'I'	System	29 Dec 2020 16:55:02

US3912076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Jan 2021 16:07:45

US3912076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '28 Jan 2021'	Tina Rountree (b) (4)	29 Jan 2021 16:07:45

US3912076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	Tina Rountree (b) (4)	29 Jan 2021 16:07:45

US3912076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	29 Jan 2021 16:07:45

US3912076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Jan 2021 16:07:55

US3912076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered '1'	System	29 Jan 2021 16:07:55

US3912076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	26 Feb 2021 15:11:18

US3912076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '26 Feb 2021'	Sandra Clancy (b) (4)	26 Feb 2021 15:11:18

US3912076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	26 Feb 2021 15:11:18

US3912076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	26 Feb 2021 15:11:18

US3912076

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	26 Feb 2021 15:11:23

US3912076

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered 'I'	System	26 Feb 2021 15:11:23

US3912076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered 'Yes (Y)'	Mia Rountree (b) (4)	24 Mar 2021 15:58:35

US3912076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered '24 Mar 2021'	Mia Rountree (b) (4)	24 Mar 2021 15:58:35

US3912076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	24 Mar 2021 15:58:35

US3912076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered 'VISIT4'	System	24 Mar 2021 15:58:35

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered empty.	System	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered empty.	System	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered empty.	System	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered empty.	System	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered empty.	System	30 Mar 2021 23:05:50

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33

US3912076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33

US3912076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered 'Yes (Y)'	Mia Rountree (b) (4)	24 Mar 2021 15:58:47

US3912076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered '24 Mar 2021'	Mia Rountree (b) (4)	24 Mar 2021 15:58:47

US3912076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered 'Yes (Y)'	Mia Rountree (b) (4)	24 Mar 2021 15:59:19

US3912076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered '24 Mar 2021'	Mia Rountree (b) (4)	24 Mar 2021 15:59:19

US3912076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered '08:55'	Mia Rountree (b) (4)	24 Mar 2021 15:59:19

US3912076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered '24 Mar 2021 08:55'	System	24 Mar 2021 15:59:19

US3912076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:47:30
User entered 'Yes (Y)'	Mia Rountree (b) (4)	24 Mar 2021 15:59:24

US3912076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:07:33
User entered 'I'	System	24 Mar 2021 15:59:24

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:53:51

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '15:08'	Mia Rountree (b) (4)	25 Nov 2020 17:53:51

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:14
User entered '23 Nov 2020 15:08'	System	25 Nov 2020 17:53:51

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Mia Rountree (b) (4)	25 Nov 2020 17:53:51

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Mia Rountree (b) (4)	25 Nov 2020 17:53:51

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 1 (Day 1)'	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '22 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '0' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered '1'	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04
	(b) (4)	

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	30 Dec 2020 18:02:32
User entered empty.	System	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04
	(b) (4)	

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Mia Rountree (b) (4)	30 Dec 2020 18:02:32
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:54:04

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 2 (Day 2)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '0'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '96'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.9' C	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Moderate (Moderate)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Moderate (Moderate)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:55:27

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 3 (Day 3)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User closed query 'Please add data through 03Dec2020. Thank you!' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:41:58
Query 'Please add data through 03Dec2020. Thank you!' answered with 'Data entered' (Site from CRA).	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:52:38
User opened query 'Please add data through 03Dec2020. Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:08:42
User entered '24 Nov 2020'	Mia Rountree (b) (4) (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '0'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '96'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.6' C	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Moderate (Moderate)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Moderate (Moderate)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	25 Nov 2020 17:56:38

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 4 (Day 4)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '25 Nov 2020'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '0'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '97'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.8' C	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 5 (Day 5)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '26 Nov 2020'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '0'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '97'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.9' C	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Moderate (Moderate)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Moderate (Moderate)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 6 (Day 6)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '27 Nov 2020'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '0'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '96'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.8' C	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 7 (Day 7)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:43:39
User entered '28 Nov 2020'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:43:42
User entered '0'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:43:44
User entered '96'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:43:57
User entered '37.1' C	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:01
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:03
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:05
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:56
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 8 (Day 8)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:14
User entered '29 Nov 2020'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:16
User entered '0'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:23
User entered '96'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:26
User entered '36.6' C	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:30
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:44:32
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:53
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 9 (Day 9)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:45:44
User entered '30 Nov 2020'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:45:46
User entered '0'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:45:48
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:45:51
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:00
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:03
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:49
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 10 (Day 10)'	Mia Rountree (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 19:51:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 19:51:18
User entered '01 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:18
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 19:51:06
User entered empty.	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered '0'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:16
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:23
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:46:48
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:51:06

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Day 11 (Day 11)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '02 Dec 2020'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '0'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '97'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User entered '%'	System	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.8' C	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Mild (Mild)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:22:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'None (None)'	Mia Rountree (b) (4)	09 Dec 2020 19:52:22

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Yes (Y)'	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 18:57:50
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Dec 2020 18:57:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	25 Nov 2020 17:57:17
	Mia Rountree (b) (4)	25 Nov 2020 17:57:17
	(b) (4)	

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[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)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:57:17

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:38

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:26
User entered '0'	System	09 Dec 2020 18:57:50

US3912076

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:22:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:49:30
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'No (N)'	Mia Rountree (b) (4)	27 Jan 2021 14:57:18

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:22:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User accepted default value 'Day 3 (Day 3)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:22:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '25 Nov 2020'	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:22:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User accepted default value 'Day 5 (Day 5)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:22:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Dec 2020 19:30:07
User entered 'NA (COVID-19 Negative) (NA)'	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '27 Nov 2020' reason for change: Data Entry Error	(b) (4)	09 Dec 2020 19:30:07
User entered empty.	Mia Rountree (b) (4)	09 Dec 2020 19:29:46
	(b) (4)	

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:22:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User accepted default value 'Day 7 (Day 7)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:22:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:47:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Dec 2020 19:30:29
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:47:57
User entered '29 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Dec 2020 19:30:29
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:22:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User accepted default value 'Day 9 (Day 9)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:22:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:48:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Dec 2020 19:31:27
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:48:00
User entered '01 Dec 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Dec 2020 19:31:27
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:22:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User accepted default value 'Day 14 (Day 14)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:22:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'NA (COVID-19 Negative) (NA)'	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:22:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User accepted default value 'Day 21 (Day 21)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:22:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'NA (COVID-19 Negative) (NA)'	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:22:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User accepted default value 'Day 28 (Day 28)'	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:22:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'NA (COVID-19 Negative) (NA)'	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Mia Rountree (b) (4)	09 Dec 2020 19:29:46

US3912076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Mia Rountree (b) (4)	25 Nov 2020 17:57:41

US3912076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 and 27NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:17:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 and 27NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).		04 Dec 2020 04:52:19
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:57:41

US3912076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	25 Nov 2020 17:57:41

US3912076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User entered 'SICKD1'	System	25 Nov 2020 17:57:41

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '15:16'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User entered '23 Nov 2020 15:16'	System	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '60.0' in	(b) (4)	
	Mia Rountree (b) (4)	25 Nov 2020 17:58:40
	(b) (4)	
DataPoint set to visible.	System	25 Nov 2020 17:57:41

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '203.0' lb	(b) (4) Mia Rountree (b) (4)	25 Nov 2020 17:58:40
DataPoint set to visible.	(b) (4) System	25 Nov 2020 17:57:41

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '36.9' C	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '82'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User entered 'bpm'	System	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '16'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User entered 'breaths/min'	System	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '134'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User entered 'mmHg'	System	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '85'	Mia Rountree (b) (4)	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User entered 'mmHg'	System	25 Nov 2020 17:58:40

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06

US3912076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06

US3912076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Mia Rountree (b) (4)	25 Nov 2020 17:58:50

US3912076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:58:50

US3912076

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:22:38

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Sample was shipped, REQ# 1F603110437' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 12:02:07
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Sample was shipped, REQ# 1F603110437' (Site from DM).	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 19:29:06
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:11:24
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	25 Nov 2020 17:59:20

US3912076

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 10:22:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '23 Nov 2020'	Mia Rountree (b) (4)	25 Nov 2020 17:59:20

US3912076

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 18:07:11
	(b) (4)	

US3912076

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 18:07:11
	(b) (4)	

US3912076

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[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 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	14 Jan 2021 18:07:11
	(b) (4)	

US3912076

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

Form: Visit Date

Generated On: 10 Jun 2021 10:22:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 18:07:11

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 18:08:33
	(b) (4)	

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[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 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	31 Mar 2021 16:05:00
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:20:18

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 18:08:33
	(b) (4)	

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:50:42
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sandra Clancy (b) (4)	31 Mar 2021 16:05:00
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:20:18

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 18:08:33
	(b) (4)	

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4)	14 Jan 2021 18:08:33
	(b) (4)	

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:46:53
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4)	14 Jan 2021 18:08:33
	(b) (4)	

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:46:53
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4)	14 Jan 2021 18:08:33
	(b) (4)	

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 18:08:33
	(b) (4)	

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'I'	System	14 Jan 2021 18:08:33

US3912076

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

Form: Unblinding

Generated On: 10 Jun 2021 10:22:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1'	System	14 Jan 2021 18:08:33

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	15 Jan 2021 22:30:25
DataPoint set to visible.	System	14 Jan 2021 18:08:33

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	15 Jan 2021 22:30:25
DataPoint set to visible.	System	14 Jan 2021 18:08:33

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User accepted default value 'Pre-Dose (PREDOSE)'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13:09'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '13 Jan 2021 13:09'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '36.9' C	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '85'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'bpm'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '11'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'breaths/min'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '100'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'mmHg'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '69'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'mmHg'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered empty.	System	15 Jan 2021 22:30:25
DataPoint set to visible.	System	14 Jan 2021 18:08:33

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User accepted default value 'Post-Dose (POSTDOSE)'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '15:20'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '13 Jan 2021 15:20'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '37.2' C	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '77'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'bpm'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '16'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'breaths/min'	System	15 Jan 2021 22:30:25

US3912076

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '109'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'mmHg'	System	15 Jan 2021 22:30:25

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '74'	Mia Rountree (b) (4)	15 Jan 2021 22:30:25
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'mmHg'	System	15 Jan 2021 22:30:25

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'No (N)'	Mia Rountree (b) (4)	15 Jan 2021 22:30:34
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	15 Jan 2021 22:30:34
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Mia Rountree (b) (4)	15 Jan 2021 22:31:24
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	15 Jan 2021 22:31:24
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

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 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	15 Jan 2021 22:31:24
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'mRNA-1273'	System	15 Jan 2021 22:31:24
DataPoint set to visible.	System	14 Jan 2021 18:08:33

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:31:24
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '14:35'	Mia Rountree (b) (4)	15 Jan 2021 22:31:24
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '13 Jan 2021 14:35'	System	15 Jan 2021 22:31:24

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Mia Rountree (b) (4)	15 Jan 2021 22:31:24
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'ONCE'	System	15 Jan 2021 22:31:24

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 22:31:24

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 18:13:33
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 18:13:33
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '12:32'	Tina Rountree (b) (4)	14 Jan 2021 18:13:33
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '13 Jan 2021 12:32'	System	14 Jan 2021 18:13:33

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 18:14:00
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:38

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 18:14:00
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '12:35'	Tina Rountree (b) (4)	14 Jan 2021 18:14:00
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:22:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '13 Jan 2021 12:35'	System	14 Jan 2021 18:14:00

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 18:14:09
	(b) (4)	

US3912076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:07:32
User entered '1'	System	14 Jan 2021 18:14:09

US3912076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4)	21 Jan 2021 20:28:38

US3912076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '21 Jan 2021'	Tina Rountree (b) (4)	21 Jan 2021 20:28:38

US3912076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered 'Contact Made (CONTACT MADE)'	Tina Rountree (b) (4)	21 Jan 2021 20:28:38

US3912076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered empty.	Tina Rountree (b) (4)	21 Jan 2021 20:28:38

US3912076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:01
User closed query 'Please complete OL-D29 eCRFs. If visit did not occur, please indicate on each form (visit date, vital signs - dosing, PE, Exposure)' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 12:16:31
Query 'Please complete OL-D29 eCRFs. If visit did not occur, please indicate on each form (visit date, vital signs - dosing, PE, Exposure)' answered with 'updated' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	18 Mar 2021 23:44:14
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	18 Mar 2021 23:43:57
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Mar 2021 23:43:57
User opened query 'Please complete OL-D29 eCRFs. If visit did not occur, please indicate on each form (visit date, vital signs - dosing, PE, Exposure)' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 19:13:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:14:18
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	21 Jan 2021 20:28:57

US3912076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User entered empty.	System	18 Mar 2021 23:43:57
User entered 'I'	System	21 Jan 2021 20:28:57

US3912076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:22:38

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User entered empty.	System	18 Mar 2021 23:43:57
User entered 'I'	System	21 Jan 2021 20:28:57
DataPoint set to visible.	System	21 Jan 2021 20:28:57

US3912076

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:22:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:53
User closed query 'Per CCGs v5.0, If COVID-19 illness sample was negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please consider adding an Adverse Event for negative COVID-19 result from Illness Visit dated 23Nov2020. ' (Site from CRA).		02 Apr 2021 12:26:03
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 96, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).		02 Apr 2021 06:01:59
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 152 and 166, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		02 Apr 2021 06:01:49
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 96, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'per follow up contact with the subject, it was determined that she had not been reading the questions thoroughly/accurately and her responses were incorrect once all was discussed with her.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	01 Apr 2021 21:43:06

US3912076

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:22:38

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 152 and 166, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE log was updated with acute anaphylaxis' (Site from DM).	Sandra Clancy (b) (4)	01 Apr 2021 21:41:24
Query 'Per CCGs v5.0, If COVID-19 illness sample was negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please consider adding an Adverse Event for negative COVID-19 result from Illness Visit dated 23Nov2020. ' answered with 'AE log updated per query request' (Site from CRA).	Sandra Clancy (b) (4)	01 Apr 2021 21:40:22
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 96, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:43:36
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 152 and 166, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:42:50

US3912076

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:22:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CCGs v5.0, If COVID-19 illness sample was negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please consider adding an Adverse Event for negative COVID-19 result from Illness Visit dated 23Nov2020. ' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) (b) (4)	25 Mar 2021 13:14:39
DataPoint Verified.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered 'Yes (Y)'	(b) (4), (b) (6) Tina Rountree (b) (4) (b) (4)	02 Feb 2021 18:01:03 29 Jan 2021 16:19:51

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Lip injury, LLT: Lip laceration - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Jan 2021 18:44:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 18:44:21
Data point term sent to Coder	System	29 Jan 2021 16:22:02
User entered 'Laceration to lip'	Tina Rountree (b) (4) (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Yes (Y)'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '24 Jan 2021'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User entered empty.	System	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '24 Jan 2021'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User entered empty.	System	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Not Related (NOT RELATED)'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'I'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	Tina Rountree (b) (4)	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User entered '0'	System	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09
User entered 'I'	System	29 Jan 2021 16:22:00

US3912076

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:09

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:01:14
Reviewed for Safety.		02 Feb 2021 14:14:27
User entered	System	02 Feb 2021 14:14:16
'USA-US211-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	02 Feb 2021 14:14:16

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:02:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Acute anaphylaxis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 22:07:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 22:07:32
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 21:52:15
User entered 'Acute Anaphylaxis'	Monique Gawlik (b) (4)	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:10
User entered 'Yes (Y)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:12
User entered 'No (N)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:14
User entered 'No (N)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User closed query 'PV Query: Please confirm the event end date (currently 31 Jan 2021) as subject was still being treated with treatment medication (prednisone) until 04 Feb 2021. Per protocol, end date should be when all symptoms resolve. ' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 18:30:43
Query 'PV Query: Please confirm the event end date (currently 31 Jan 2021) as subject was still being treated with treatment medication (prednisone) until 04 Feb 2021. Per protocol, end date should be when all symptoms resolve. ' answered with 'the end date is correct - all symptoms had resolved and she was released from the local ER. see updated narrative below.' (Site from Safety).	Sandra Clancy (b) (4)	04 Mar 2021 22:31:29
User opened query 'PV Query: Please confirm the event end date (currently 31 Jan 2021) as subject was still being treated with treatment medication (prednisone) until 04 Feb 2021. Per protocol, end date should be when all symptoms resolve. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 22:19:33
DataPoint Verified.		02 Feb 2021 18:02:17
User entered '31 Jan 2021'	Monique Gawlik (b) (4)	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4)	02 Feb 2021 18:02:19
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:52:00
	Monique Gawlik (b) (4)	

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:21
User entered 'No (N)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	01 Feb 2021 22:33:44
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:23
User entered '31 Jan 2021' reason for change: Data Entry Error	Monique Gawlik (b) (4)	01 Feb 2021 22:33:44
User entered empty.	Monique Gawlik (b) (4)	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4)	02 Feb 2021 18:02:26
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:52:00
	Monique Gawlik (b) (4)	

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:28
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:30
User entered 'Yes (Y)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4)	02 Feb 2021 18:02:32
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 21:52:00
	Monique Gawlik (b) (4)	

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:34
User entered 'I'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:02:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		02 Feb 2021 06:13:48
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Discharged from ER same day. Please accept.' (Site from System).	Monique Gawlik (b) (4)	01 Feb 2021 22:10:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Feb 2021 21:52:00
User entered '0'	Monique Gawlik (b) (4)	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:38
User entered empty.	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4)	02 Feb 2021 18:02:40
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:52:00
	Monique Gawlik (b) (4)	

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:42
User entered 'No (N)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:44
User entered empty.	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:46
User entered '0'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:48
User entered '0'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:02:52
User entered '0'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:12
User entered 'Not Related (NOT RELATED)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:14
User entered 'Not Related (NOT RELATED)'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record that match this information. Please also note that this was after the 2 doses of vaccines being studies. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 11:29:18
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record that match this information. Please also note that this was after the 2 doses of vaccines being studies. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'dosing discontinuation eCRF completed' (Site from DM).	Sandra Clancy (b) (4)	04 Mar 2021 23:11:01
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record that match this information. Please also note that this was after the 2 doses of vaccines being studies. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:51:28
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:05:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Monique Gawlik (b) (4)	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:16
User entered '0'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:19
User entered 'I'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:21
User entered '0'	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Monique Gawlik (b) (4) [REDACTED]	01 Feb 2021 22:33:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Monique Gawlik (b) (4) [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:25
User entered empty.	Monique Gawlik (b) (4) [REDACTED] [REDACTED]	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:32:06
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User closed query 'PV Query: Please confirm action taken with mRNA-1273 as dosing discontinuation is blank.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:30:48
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		05 Mar 2021 18:30:33
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		05 Mar 2021 18:30:28
Query 'PV Query: Please confirm action taken with mRNA-1273 as dosing discontinuation is blank.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	04 Mar 2021 23:11:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'no labs or diagnostic testing as the stay in the ER was less than 4 hours' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	04 Mar 2021 22:51:24
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no covid testing as subject was not admitted' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	04 Mar 2021 22:50:31

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD AN ALLERGIC REACTION TO UNKNOWN ALLERGEN AND WAS TREATED AND RELEASED FROM EMERGENCY ROOM. SUBJECT PRESENTED TO ER WITH COMPLAINTS OF URTICARIA, PRURITIS AND THROAT SWELLING. SHE STATED THAT HER THROAT FELT SWOLLEN AND WAS HAVING SEVERE DYSPNEA AND CHEST TIGHTNESS. UPON EXAMINATION, IT WAS NOTED THAT SHE APPEARED ILL AND IN DISTRESS; SHE WAS TACHYCARDIC, HAD AUDIBLE WHEEZING BUT NO LIP OR TONGUE SWELLING. THERE WAS NO OROPHARYNGEAL OR LIP SWELLING; SKIN EXAM POSITIVE FOR DIFFUSE URTICARIA. She was treated with IM EpiPen upon arrival; immediately throat swelling and chest pain had resolved. Since the subject did not have a history of anaphylaxis, she was observed for 3 hours to ensure no rebound anaphylaxis and was later discharged in stable condition.' reason for change: Data Entry Error DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	04 Mar 2021 22:49:07
	Sandra Clancy (b) (4) (b) (4)	04 Mar 2021 22:41:36
User entered 'SUBJECT HAD AN ALLERGIC REACTION TO UNKNOWN ALLERGEN AND WAS TREATED AND RELEASED FROM EMERGENCY ROOM.	Sandra Clancy (b) (4) (b) (4)	04 Mar 2021 22:41:36
subject presented to ER with complaints of urticaria, pruritis and throat swelling. She stated that her throat felt swollen and was having severe dyspnea and chest tightness. Upon examination, it was noted that she appeared ill and in distress; she was tachycardic, had audible wheezing but no lip or tongue swelling. There as no oropharyngeal or lip swelling; skin exam positive for diffuse urticaria.' reason for change: Data Entry Error		
User opened query 'PV Query: Please confirm action taken with mRNA-1273 as dosing discontinuation is blank.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	19 Feb 2021 22:19:59

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 19:34:55
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'con med are in EDC' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 22:22:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:11:00
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		08 Feb 2021 19:10:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		08 Feb 2021 19:10:25
DataPoint Verified.		02 Feb 2021 18:05:27
User entered 'Subject had an allergic reaction to unknown allergen and was treated and released from emergency room.'	Monique Gawlik (b) (4)	01 Feb 2021 21:52:00

PRODUCTION RELEASE (v12.003
EAB) (1725)

2214 of 2703

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Feb 2021 21:52:00

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Insulin-dependent diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Feb 2021 13:10:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 13:10:56
Data point term sent to Coder	System	21 Feb 2021 21:18:10
User entered 'insulin dependent diabetes mellitus'	(b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 23:19:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 23:19:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	04 Mar 2021 23:19:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Feb 2021 21:17:11
User entered empty.	(b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Feb 2021 21:18:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Feb 2021 21:18:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Feb 2021 21:18:11
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Feb 2021 21:17:11
User entered empty.	(b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Feb 2021 21:18:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Feb 2021 21:18:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Feb 2021 21:18:11
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Feb 2021 21:17:11
User entered empty.	(b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Feb 2021 21:18:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Feb 2021 21:18:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Feb 2021 21:18:11
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Feb 2021 21:17:11
User entered empty.	(b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Feb 2021 21:17:11

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 13:36:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 13:36:46
Data point term sent to Coder	System	26 Mar 2021 13:35:28
User entered 'Worsening of asthma'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'Yes (Y)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	02 Apr 2021 15:35:44
User closed query 'Per eCRF Guidelines v5.0, "Events with SAR checked on Adverse Events eCRF page should be limited ONLY to those terms on the diary." Please correct, or clarify. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:25:29
Query 'Per eCRF Guidelines v5.0, "Events with SAR checked on Adverse Events eCRF page should be limited ONLY to those terms on the diary." Please correct, or clarify. ' answered with 'corrected per query' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	01 Apr 2021 21:39:28
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	01 Apr 2021 21:38:45
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	01 Apr 2021 21:38:45
User opened query 'Per eCRF Guidelines v5.0, "Events with SAR checked on Adverse Events eCRF page should be limited ONLY to those terms on the diary." Please correct, or clarify. ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:16:24
Query 'Per eCRF Guidelines v5.0, "Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner including an illness visit." Please correct, or clarify. ' canceled (Site from CRA).		30 Mar 2021 18:16:18
User opened query 'Per eCRF Guidelines v5.0, "Medically attended AEs are defined as any AEs that lead to an unscheduled visit to a healthcare practitioner including an illness visit." Please correct, or clarify. ' (Site from CRA).		30 Mar 2021 18:16:15
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:22:48
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'No (N)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '23 Nov 2020'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User entered empty.	System	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'No (N)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '05 Dec 2020'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User entered empty.	System	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'No (N)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'Not Applicable (NOT APPLICABLE)'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'I'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Mar 2021 13:34:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 13:34:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mia Rountree (b) (4)	26 Mar 2021 13:34:45
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 13:34:39
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39
	(b) (4)	

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User entered '0'	System	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14
User entered 'I'	System	26 Mar 2021 13:34:39

US3912076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:22:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:24:14

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:22:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:53
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:34
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:54:17

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS, PRODUCT: AMLODIPINE;OLMESARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Sep 2020 00:56:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 00:56:42
Data point term sent to Coder	System	07 Sep 2020 00:55:48
User entered 'amlodipine/olmesartan'	Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:55:40

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'hypertension'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	01 Apr 2021 22:14:32
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	01 Apr 2021 19:15:21
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'l'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'tablet (TABLET)'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'once daily (QD)'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'un Aug 2019'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:55:40
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:55:40

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:55:40

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Sep 2020 00:55:40

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM, PRODUCTSYNONYM: CARDIZEM [DILTIAZEM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 20:18:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 20:18:27
Data point term sent to Coder Coding entries removed.	System Mia Rountree (b) (4)	03 Feb 2021 20:17:25 03 Feb 2021 20:17:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM, PRODUCTSYNONYM: CARDIZEM [DILTIAZEM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Sep 2020 05:38:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:38:42
Data point term sent to Coder User entered 'cardizem'	System Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:56:48 07 Sep 2020 00:56:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User closed query 'Please confirm spelling: hypertension or hyoertension. Thank you!' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 14:49:29
Query 'Please confirm spelling: hypertension or hyoertension. Thank you!' answered with 'Data corrected' (Site from CRA).	Mia Rountree (b) (4)	03 Feb 2021 20:17:20
User entered 'HYPERTENSION' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 20:17:08
User opened query 'Please confirm spelling: hypertension or hyoertension. Thank you!' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:06:29
User entered 'hyoertension'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '120'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'mg (mg)'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'once daily (QD)'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'un Aug 2019'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:56:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:56:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:56:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Sep 2020 00:56:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
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 SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Sep 2020 00:58:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Sep 2020 00:58:43
Data point term sent to Coder	System	07 Sep 2020 00:57:49
User entered 'synthroid'	Tina Rountree (b) (4) (b) (4)	07 Sep 2020 00:57:22

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'hypothyroidism'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '150'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Other (OTHER)'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'mcg'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'once daily (QD)'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'un UNK 1991'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:57:22
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:57:22

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:57:22

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Sep 2020 00:57:22

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 00:59:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 00:59:44
Data point term sent to Coder	System	07 Sep 2020 00:58:49
User entered 'aspirin'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'cardiac prophylaxis'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '81'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'mg (mg)'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'once daily (QD)'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'un UNK 2015'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:58:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:58:16

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:58:16

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Sep 2020 00:58:16

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Sep 2020 01:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 01:00:44
Data point term sent to Coder	System	07 Sep 2020 00:59:49
User entered 'singulair'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'asthma'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '10'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'mg (mg)'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'once daily (QD)'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'un UNK 2019'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 00:59:16
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:59:16

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 00:59:16

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Sep 2020 00:59:16

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Sep 2020 01:01:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 01:01:45
Data point term sent to Coder	System	07 Sep 2020 01:00:51
User entered 'Albuterol sulfate'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'asthma'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '1'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Other (OTHER)'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'solution'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'as needed (PRN)'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Tina Rountree (b) (4) (b) (4)	07 Sep 2020 01:00:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'un UNK 2004'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 01:00:31
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Sep 2020 01:00:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Sep 2020 01:00:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Sep 2020 01:00:31

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE, PRODUCTSYNONYM: EPIPEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 12:37:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:37:44
Data point term sent to Coder	System	03 Feb 2021 20:28:56
User entered 'Epipen'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:28:08
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Acute anaphylaxis'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0.3'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:28:08
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'once (ONCE)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:28:08
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
DataPoint Verified.		01 Apr 2021 19:07:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:28:08
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
User entered empty.	System	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
User entered empty.	System	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:42
User entered empty.	System	03 Feb 2021 20:28:08

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.	(b) (4)	01 Apr 2021 19:06:08
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:17:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:17:46
Data point term sent to Coder	System	03 Feb 2021 20:29:57
User entered 'Albuterol 0.083%'	Mia Rountree (b) (4)	03 Feb 2021 20:29:42
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:10
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Acute anaphylaxis'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '2.5'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:16
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:29:42
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:19
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:29:42
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'once (ONCE)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:24
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:29:42
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:27
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:30
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:29:42
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
DataPoint Verified.		01 Apr 2021 19:06:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
User entered empty.	System	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
User entered empty.	System	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:50
User entered empty.	System	03 Feb 2021 20:29:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Feb 2021 20:45:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 20:45:57
Data point term sent to Coder	System	03 Feb 2021 20:31:58
User entered 'Pepcid'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:10
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Acute anaphylaxis'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:12
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '20'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:17
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:31:15
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'once (ONCE)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:31:15
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:31:15
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:29
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:31:15
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:31:15
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:49
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
DataPoint Verified.		01 Apr 2021 19:05:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:31:15
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
User entered empty.	System	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
User entered empty.	System	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:06:57
User entered empty.	System	03 Feb 2021 20:31:15

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.	(b) (4)	01 Apr 2021 19:04:02
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Feb 2021 11:47:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 11:47:53
Data point term sent to Coder	System	03 Feb 2021 20:33:01
User entered 'Solumedrol'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:05
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:32:11
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:08
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Acute anaphylaxis'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.	(b) (4)	01 Apr 2021 19:04:11
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '125'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:32:11
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:13
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:32:11
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.	(b) (4)	01 Apr 2021 19:04:16
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:32:11
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:18
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'once (ONCE)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:32:11
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:24
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:32:11
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.	(b) (4)	01 Apr 2021 19:04:31
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:45
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.		01 Apr 2021 19:04:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
DataPoint Verified.	(b) (4)	01 Apr 2021 19:04:53
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
User entered empty.	System	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
User entered empty.	System	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:07:02
User entered empty.	System	03 Feb 2021 20:32:11

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:13
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: ALPHA- AND BETA-ADRENORECEPTOR AGONISTS, PRODUCT: EPINEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: EPINEPHRINE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 21:17:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 21:17:08
Data point term sent to Coder	System	03 Feb 2021 20:33:01
User entered 'Epinephrine HCl'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:33:00

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:18
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Acute anaphylaxis'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0.3'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:32
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:33:00

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:35
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'once (ONCE)'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:33:00
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:33:00
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:49
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:33:00
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '31 Jan 2021'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:33:00

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
DataPoint Verified.		12 Apr 2021 20:20:03
DataPoint Un-verified.		12 Apr 2021 20:19:58
DataPoint Verified.		01 Apr 2021 19:02:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	03 Feb 2021 20:33:00
	Mia Rountree (b) (4)	
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
User entered empty.	System	03 Feb 2021 20:33:00

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
User entered empty.	System	03 Feb 2021 20:33:00

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:06
User entered empty.	System	03 Feb 2021 20:33:00

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:24
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 12:02:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:02:44
Data point term sent to Coder	System	03 Feb 2021 20:34:02
User entered 'Benadryl'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:30
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Acute anaphylaxis'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '25'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:39
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'as needed (PRN)'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:49
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Oral (ORAL)'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:53
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).		19 Mar 2021 12:36:55
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'information transcribed from medical records' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	18 Mar 2021 23:45:20
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:23:24
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered '01 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:01:57
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:39:29
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'it's taken as needed and is intended to be used in the event of another episode.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	18 Mar 2021 23:45:59
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:23:33
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:02:00
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 19:02:02
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	Mia Rountree (b) (4)	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 20:33:42

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:09:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:09:31
Data point term sent to Coder	System	22 Mar 2021 19:11:06
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:10:22
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 20:45:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 20:45:56
Data point term sent to Coder	System	03 Feb 2021 20:36:04
User entered 'Pepcid'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:37
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:32
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	22 Mar 2021 19:10:22
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Mar 2021 19:10:22
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'No (N)'	Mia Rountree (b) (4)	03 Feb 2021 20:35:05
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:40
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:32
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	22 Mar 2021 19:10:22
	(b) (4)	
User entered 'GI prophylaxis' reason for change:	Sandra Clancy (b) (4)	22 Mar 2021 19:10:22
Data Entry Error	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Acute anaphylaxis'	Mia Rountree (b) (4)	03 Feb 2021 20:35:05
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '20'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:45
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:05
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:48
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'as needed (PRN)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:05
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:53
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Oral (ORAL)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:05
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:57
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).		23 Mar 2021 06:47:48
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'event updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:11:16
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:24:20
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered '01 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 18:59:59
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.	(b) (4)	01 Apr 2021 19:00:02
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:32
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:47:51
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4)	22 Mar 2021 19:11:44
Signature has been broken.	Sandra Clancy (b) (4)	22 Mar 2021 19:10:53
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Mar 2021 19:10:53
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:24:30
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Yes (Y)'	Mia Rountree (b) (4)	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.	(b) (4)	01 Apr 2021 19:00:04
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:32
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	22 Mar 2021 19:10:53
	(b) (4)	
User entered '4 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Mar 2021 19:10:53
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 20:35:05
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
DataPoint Verified.		01 Apr 2021 19:00:07
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:05
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
User entered empty.	System	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
User entered empty.	System	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:05
User entered empty.	System	03 Feb 2021 20:35:05

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.	(b) (4)	01 Apr 2021 18:58:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 11:26:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:26:43
Data point term sent to Coder	System	03 Feb 2021 20:36:05
User entered 'Prednisone'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:58:53
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:58:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Acute anaphylaxis'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:58:58
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	26 Feb 2021 15:12:36
	(b) (4)	
User entered '20' reason for change: Data Entry Error	Sandra Clancy (b) (4)	26 Feb 2021 15:12:36
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Unknown'	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:01
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	26 Feb 2021 15:12:36
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	26 Feb 2021 15:12:36
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'tablet (TABLET)'	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:59:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	26 Feb 2021 15:34:46
User entered 'once daily (QD)' reason for change: Data Entry Error	System	26 Feb 2021 15:34:46
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	26 Feb 2021 15:12:36
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Sandra Clancy (b) (4)	26 Feb 2021 15:12:36
User entered 'unknown (UNKNOWN)'	(b) (4)	
	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:59:08
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:59:11
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Oral (ORAL)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:59:13
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:59:16
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		23 Mar 2021 06:48:06
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:13:23
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:27:02
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered '01 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:59:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:27
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)' reason for change: New Information	(b) (4) Tina Rountree (b) (4)	04 Feb 2021 23:51:24
User entered 'Yes (Y)'	(b) (4) Mia Rountree (b) (4)	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.	(b) (4)	01 Apr 2021 18:59:25
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '4 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Tina Rountree (b) (4)	04 Feb 2021 23:51:24
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 20:35:57
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
DataPoint Verified.		01 Apr 2021 18:59:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
User entered '1'	System	26 Feb 2021 15:34:46
User entered empty.	System	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
User entered '1'	System	26 Feb 2021 15:34:46
User entered empty.	System	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:13
User entered '804 (804)'	System	26 Feb 2021 15:34:46
User entered empty.	System	03 Feb 2021 20:35:57

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.	(b) (4)	01 Apr 2021 18:58:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:09:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:09:41
Data point term sent to Coder	System	22 Mar 2021 19:21:16
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:20:28
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:52:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:52:51
Data point term sent to Coder	System	03 Feb 2021 20:37:06
User entered 'Zyrtec'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.	(b) (4)	01 Apr 2021 18:58:16
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.	(b) (4)	01 Apr 2021 18:58:18
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:32
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	22 Mar 2021 19:20:28
	(b) (4)	
User entered 'post acute anaphylaxis' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Mar 2021 19:20:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Acute anaphylaxis'	Mia Rountree (b) (4)	03 Feb 2021 20:36:33
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:20
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '10'	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:36:33
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'mg (mg)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:24
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:36:33
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'as needed (PRN)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:29
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	03 Feb 2021 20:36:33
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:31
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Oral (ORAL)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:35
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).		23 Mar 2021 06:48:17
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'it is a discharge medication' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:20:50
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:27:25
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered '01 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.		01 Apr 2021 18:58:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.	(b) (4)	01 Apr 2021 18:58:39
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:32
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 06:48:19
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:21:11
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:20:28
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:20:28
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:27:33
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.	(b) (4)	01 Apr 2021 18:58:41
User signature succeeded.	Mark Hutchens (b) (4)	23 Mar 2021 18:26:32
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	22 Mar 2021 19:20:28
	(b) (4)	
User entered '2 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Mar 2021 19:20:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	03 Feb 2021 20:36:33
	(b) (4)	

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
DataPoint Verified.	(b) (4)	01 Apr 2021 18:58:44
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	(b) (4) Mia Rountree (b) (4) (b) (4)	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
User entered empty.	System	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
User entered empty.	System	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:22
User entered empty.	System	03 Feb 2021 20:36:33

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Feb 2021 18:43:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 18:43:45
Data point term sent to Coder	System	04 Feb 2021 23:55:45
User entered 'albuterol sulfate inhaler'	Tina Rountree (b) (4) (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'acute anaphylaxis'	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '2'	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'puff (PUFF)'	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:48
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4) Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:50
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'as needed (PRN)'	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:52
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	(b) (4) Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Tina Rountree (b) (4) (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:57:59
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).		23 Mar 2021 06:48:33
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'medication provided at discharge - entry is correct' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:15:35
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:27:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered '1 Feb 2021'	Tina Rountree (b) (4) (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:58:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered '0'	(b) (4) Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:58:03
User closed query ' Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:48:36
Query ' Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'this is rescue medication and it was provided at discharge - as such it is used as needed.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Mar 2021 19:17:33
User opened query ' Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:27:59
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:13:42
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:58:05
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered empty.	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:58:06
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'No (N)'	Tina Rountree (b) (4)	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 23:54:45

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: FIASP - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Feb 2021 12:15:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 12:15:11
Data point term sent to Coder	System	21 Feb 2021 21:08:06
User entered 'Fiasp (insulin aspart) before meals'	(b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'insulin dependent diabetic mellitus'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '10-15'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User closed query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:25:44
Query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' answered with 'Data corrected' (Site from DM).	Mia Rountree (b) (4)	26 Feb 2021 18:03:49
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 18:03:37
User opened query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:47:32
User entered 'Other (OTHER)'		21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	26 Feb 2021 18:03:37
	(b) (4)	
User entered 'units'	(b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 21:07:39

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC, PRODUCTSYNONYM: TRESIBA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:14:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:54:34
Data point term sent to Coder	System	21 Feb 2021 21:15:08
User entered 'tresiba (insulin100u/ml long acting at bedtime)'	(b) (4), (b) (6) (b) (4)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'insulin dependent diabetic mellitus'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '25'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User closed query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:25:59
Query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' answered with 'Data corrected' (Site from DM).	Mia Rountree (b) (4)	26 Feb 2021 18:04:44
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 18:04:22
User opened query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'UNITS'. However, instead of entering Other-UNITS, if appropriate please consider selecting 'IU' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:47:52
User entered 'Other (OTHER)'		21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	26 Feb 2021 18:04:22
	(b) (4)	
User entered 'units'	(b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered empty.	(b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Feb 2021 21:14:47

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 10:56:08
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 Mar 2021 10:56:08
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:22:48
Data point term sent to Coder	System	26 Mar 2021 13:46:32
User entered 'Prednisone (5mg tapered dose)'	Mia Rountree (b) (4) (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'No (N)'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'Worsening of asthma'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '60'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'mg (mg)'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'once daily (QD)'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'Oral (ORAL)'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered empty.	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '23 Nov 2020'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '0'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'No (N)'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered '04 Dec 2020'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:48
User entered 'No (N)'	Mia Rountree (b) (4)	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User entered '1'	System	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User entered '1'	System	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:32
User entered '804 (804)'	System	26 Mar 2021 13:45:48

US3912076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:22:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:53
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
User entered 'Yes (Y)' reason for change: New Information	Tina Rountree (b) (4)	29 Jan 2021 16:22:13
User entered 'No (N)'	Tina Rountree (b) (4)	07 Sep 2020 01:00:43

US3912076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '24 Jan 2021'	Tina Rountree (b) (4)	29 Jan 2021 16:22:48
	(b) (4)	

US3912076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered '2 stitches to lip'	Tina Rountree (b) (4)	29 Jan 2021 16:22:48
	(b) (4)	

US3912076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4)	29 Jan 2021 16:22:48
	(b) (4)	

US3912076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:38

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:13:42
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	29 Jan 2021 16:22:48
	(b) (4)	

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'USA-US211-2021-MRNA-1273-P301000001'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Mark'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Timothy'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Hutchens'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Vachris'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4)	10 Feb 2021 19:35:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:07:59
User entered 'US'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '3'	System	10 Feb 2021 19:58:59
User entered '2'	System	10 Feb 2021 19:35:37
User entered '1'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'USA-US211-2021-MRNA-1273-P301000001'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Mark'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Timothy'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Hutchens'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Vachris'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4)	10 Feb 2021 19:35:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:07:59
User entered 'US'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '3'	System	10 Feb 2021 19:58:59
User entered '2'	System	10 Feb 2021 19:35:37
User entered '1'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:22:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:07:59
User entered '02/Feb/2021 14:14'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:22:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 20:35:19
DataPoint Verified.		02 Feb 2021 18:07:59
User entered 'I'		02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'USA-US211-2021-MRNA-1273-P301000001'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Mark'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'Timothy'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Hutchens'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'Vachris'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:35:13
DataPoint Verified.		02 Feb 2021 18:07:59
User entered 'US'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '3'	System	10 Feb 2021 19:58:59
User entered '2'	System	10 Feb 2021 19:35:37
User entered '1'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:22:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '10/Feb/2021 14:35'	(b) (4) System	10 Feb 2021 19:35:37

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:22:38

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)	15 Mar 2021 20:36:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:19
User entered '1'		10 Feb 2021 19:35:37

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'USA-US211-2021-MRNA-1273-P301000001'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Mark'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Timothy'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Hutchens'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Vachris'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:35:13
DataPoint Verified.		02 Feb 2021 18:07:59
User entered 'US'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '3'	System	10 Feb 2021 19:58:59
User entered '2'	System	10 Feb 2021 19:35:37
User entered '1'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:22:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
User entered '10/Feb/2021 14:58'	(b) (4) System	10 Feb 2021 19:58:59

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:22:38

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)	15 Mar 2021 20:36:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:19
User entered '1'		10 Feb 2021 19:58:59

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'USA-US211-2021-MRNA-1273-P301000001'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Yes (Y)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'No (N)'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Mark'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:07:59
Reviewed for Safety.		02 Feb 2021 14:14:47
User entered 'Timothy'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
Un-reviewed for Safety.	(b) (4)	05 Mar 2021 14:49:15
DataPoint Un-verified.	System	05 Mar 2021 14:49:15
Signature has been broken.	System	05 Mar 2021 14:49:15
User entered 'Hutchens'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
DataPoint Verified.	(b) (4)	02 Feb 2021 18:07:59
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 14:14:47
User entered 'Vachris'	System	02 Feb 2021 14:14:16

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:35:13
DataPoint Verified.		02 Feb 2021 18:07:59
User entered 'US'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:22:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 14:49:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:14:18
	(b) (4)	
User entered '3'	System	10 Feb 2021 19:58:59
User entered '2'	System	10 Feb 2021 19:35:37
User entered '1'	System	02 Feb 2021 14:14:54

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:22:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 20:36:25
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered '05/Mar/2021 09:49'	(b) (4) System	05 Mar 2021 14:49:15

US3912076

Folder: SAE USA-US211-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:22:38

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)	15 Mar 2021 20:36:25
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:54:34
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 14:49:15