

US3912046 (Prod: Synexus - Optimal Research - Austin)

Generated By: (b) (6)

Generated On: 11 Jun 2021 15:10:15

All time stamps listed in this document are displayed in GMT

US3912046

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

[Participant ID](#)

US3912046

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

US3912046

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3912046

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3912046

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	HYPERLIPEDEMIA
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)	

US3912046

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	ASPERGERS SYNDROME
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3912046

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	DIABETIC NEUROPATHY - BILATERAL FEET
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 15:57:49

Generated On: 11 Jun 2021 15:10:15

Condition	OBESITY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3912046

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:41 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:41
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	231 lb
BMI (<i>xxx.x</i>)	33.21435 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:05:56

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PUBLIC TRANSIT 3 TIMES PER WEEK

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145280

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Height	ND - Not Done
Weight	ND - Not Done

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

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)	31 AUG 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:41
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

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)	31 AUG 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 13:22 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 13:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	12:11 (24 HR)
Collection date and time (derived)	31 AUG 2020 12:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:16	31 AUG 2020 12:16
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 14:10

PC Open Date & Time

31 AUG 2020 13:42

PC Close Date & Time

31 AUG 2020 16:12

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 ☒

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	31 AUG 2020 23:24
PC Open Date & Time	31 AUG 2020 17:07
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 16:20

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

98.5 °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 13:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

98.6 °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

03 SEP 2020 13:34

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 13:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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 07:03

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

99.4 °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

06 SEP 2020 16:35

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

31 AUG 2020 14:11

PC Open Date & Time

31 AUG 2020 13:42

PC Close Date & Time

31 AUG 2020 16:12

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

31 AUG 2020 21:07

PC Open Date & Time

31 AUG 2020 17:07

PC Close Date & Time

01 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 ☐

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

2

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 - **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 SEP 2020 16:21

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 SEP 2020 13:46

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 SEP 2020 13:34

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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 SEP 2020 13:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

06 SEP 2020 07:03

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

06 SEP 2020 16:35

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 14:12
PC Open Date & Time	31 AUG 2020 13:42
PC Close Date & Time	31 AUG 2020 16:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

No ☐

Yes ☒

PC Time stamp	31 AUG 2020 21:06
PC Open Date & Time	31 AUG 2020 17:07
PC Close Date & Time	01 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 2723

EAB) (1725)

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 16:21
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 2723

EAB) (1725)

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:47
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 2723

EAB) (1725)

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:35
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

55 of 2723

EAB) (1725)

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 13:47
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

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 2723

EAB) (1725)

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 07:04
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

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
EAB) (1725)

59 of 2723

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:36
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3912046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

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

Visit date (dd MMM yyyy)	28 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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US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

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)	28 SEP 2020
Time of assessment (00:00-23:59)	09:38 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:38
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

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)	28 SEP 2020
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:52
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3912046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:07 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:07

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

US3912046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	10:04 (24 HR)
Collection date and time (derived)	28 SEP 2020 10:04

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:11	28 SEP 2020 10:11
Nasopharyngeal Swab 2	No		

US3912046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 12:02

PC Open Date & Time

28 SEP 2020 11:27

PC Close Date & Time

28 SEP 2020 13:57

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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	29 SEP 2020 10:56
PC Open Date & Time	28 SEP 2020 14:52
PC Close Date & Time	29 SEP 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

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

30 SEP 2020 04:57

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

01 OCT 2020 07:35

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

95.6 °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

02 OCT 2020 07:26

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

98.2 °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

02 OCT 2020 18:48

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

03 OCT 2020 13:57

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 ☐

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

1

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 - **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

28 SEP 2020 12:03

PC Open Date & Time

28 SEP 2020 11:27

PC Close Date & Time

28 SEP 2020 13:57

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

29 SEP 2020 10:56

PC Open Date & Time

28 SEP 2020 14:52

PC Close Date & Time

29 SEP 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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

30 SEP 2020 04:58

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

01 OCT 2020 07:36

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

01 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

02 OCT 2020 18:49

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

03 OCT 2020 13:57

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

04 OCT 2020 12:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 12:04
PC Open Date & Time	28 SEP 2020 11:27
PC Close Date & Time	28 SEP 2020 13:57

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:57
PC Open Date & Time	28 SEP 2020 14:52
PC Close Date & Time	29 SEP 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 ☒

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 04:59
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

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EAB) (1725)

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 07:37
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 2723

EAB) (1725)

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

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
EAB) (1725)

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US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 18:49
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

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EAB) (1725)

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:58
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

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EAB) (1725)

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CALLED SUBJECT FIVE TIMES
FROM THE 12TH TO THE 16 AND
NO ANSWER, LEFT MESSAGES.

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 09:00
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

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.

US3912046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 NOV 2020

Collection time (00:00-23:59)

09:33 (24 HR)

Collection date and time (derived)

2 NOV 2020 09:33

US3912046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:06:23

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 NOV 2020 12:37:22
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

07 NOV 2020 09:12:31

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

14 NOV 2020 07:40:15

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☒

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 NOV 2020 15:06:38

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 19:08:01

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 09:08:36
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

09 DEC 2020 08:45:29

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

16 DEC 2020 23:28:34

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
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	23 DEC 2020 20:24:57
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

30 DEC 2020 07:14:15

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 09:28:29

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

13 JAN 2021 13:30:00

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 07:18:06

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 11:48:42

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

03 FEB 2021 00:03:38

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 166

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 13:54:17
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

03 MAR 2021 18:38:38

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

10 MAR 2021 10:24:26

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

17 MAR 2021 00:35:58

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 <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	25 MAR 2021 09:57:33
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 <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	31 MAR 2021 17:08:27
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

07 APR 2021 08:06:46

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

14 APR 2021 15:46:03

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

21 APR 2021 22:24:06

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

28 APR 2021 08:29:41

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 250

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 264

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 271

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

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

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

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

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

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

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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"/>

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐
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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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"/>

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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"/>

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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°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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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°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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐
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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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"/>

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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°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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐ 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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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13 MAR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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23 MAR 2022 00:01

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27 MAR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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03 APR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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06 APR 2022 00:01

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10 APR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

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17 APR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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"/>

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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24 APR 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

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01 MAY 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐ 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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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15 MAY 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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05 JUN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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12 JUN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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19 JUN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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26 JUN 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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03 JUL 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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10 JUL 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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13 JUL 2022 00:01

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17 JUL 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐
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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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24 JUL 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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27 JUL 2022 00:01

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31 JUL 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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07 AUG 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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10 AUG 2022 00:01

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14 AUG 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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21 AUG 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

Date and time of submission

Patient Cloud Open Date & Time	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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"/>

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3912046

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Jun 2021 15:10:15

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:14:21

US3912046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:56

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 19:52:59

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:52:59

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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 _____

US3912046

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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)	

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

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.

US3912046

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Date of Contact	26 OCT 2020
Time of Contact	08:53
Date and Time of Contact (derived)	26 OCT 2020 08:53
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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"/>

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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 ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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 OCT 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.4 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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 ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Date of Visit 26 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 26 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	09:06 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 09:06
Height (xxx.x)	70.0 in
Weight (xxx.x)	234.0 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3912046

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 16:05:55

Generated On: 11 Jun 2021 15:10:15

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3912046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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 _____

US3912046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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)	

US3912046

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

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.

US3912046

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Jun 2021 15:10:15

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	
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US3912046

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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

Visit date (dd MMM yyyy)	13 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3912046

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 19:52:59

Generated On: 11 Jun 2021 15:10:15

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

US3912046

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Mar 2021 18:25:55

Generated On: 11 Jun 2021 15:10:15

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

US3912046

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 18:25:55

Generated On: 11 Jun 2021 15:10:15

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)	26 FEB 2021
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 13:55
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3912046

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 18:25:55

Generated On: 11 Jun 2021 15:10:15

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)	26 FEB 2021
Time of assessment (00:00-23:59)	16:03 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 16:03
Temperature (xxx.x)	97.7 F
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3912046

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

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 18:25:55

Generated On: 11 Jun 2021 15:10:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3912046

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

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 19:10:21

Generated On: 11 Jun 2021 15:10:15

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) 26 FEB 2021

What was the treatment time? (00:00-23:59) 15:27 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 15:27

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

US3912046

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

14:29 (24 HR)

Collection date and time (derived)

13 JAN 2021 14:29

US3912046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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

Collection date (dd MMM yyyy)	13 JAN 2021
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Collection time (00:00 - 23:59)	14:31
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Collection Date and Time (derived)	13 JAN 2021 14:31
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US3912046

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 19:10:21

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 19:10:21

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 17:08:17

Generated On: 11 Jun 2021 15:10:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 17:08:17

Generated On: 11 Jun 2021 15:10:15

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)	14 APR 2021
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	14 APR 2021 13:06
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	086 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	088 mmHg
Diastolic Blood Pressure units	MMHG

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 17:08:17

Generated On: 11 Jun 2021 15:10:15

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)	14 APR 2021
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	14 APR 2021 15:58
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	086 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG

US3912046

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 17:08:16

Generated On: 11 Jun 2021 15:10:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 APR 2021

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

US3912046

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 17:08:16

Generated On: 11 Jun 2021 15:10:15

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) 14 APR 2021

What was the treatment time? (00:00-23:59) 15:17 (24 HR)

Treatment Date and Time (derived) 14 APR 2021 15:17

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

US3912046

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 17:08:16

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:50:47

Generated On: 11 Jun 2021 15:10:15

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3912046

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:50:47

Generated On: 11 Jun 2021 15:10:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912046

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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 _____

US3912046

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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)	

US3912046

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

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.

US3912046

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3912046

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

AEID

Adverse event

HYPERTENSION (WORSENING
OF)

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)

08 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 SEP 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 ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

AEID	
Adverse event	HYPERTENSION (WORSENING OF)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

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	True
Concomitant Medication	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

AEID	USA-US211-2021-MRNA-1273-P30 1000003
Adverse event	ACUTE PONTINE INFARCT
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)	22 MAR 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)	30 MAR 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	True
Hospital Admission Date (dd MMM yyyy)	22 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	30 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	LEFT HEMIPARESIS; DYSPHAGIA
Narrative	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

THE SUBJECT PRESENTED TO
LOCAL ER VIA AMBULANCE
ON 22MAR2021 WITH
COMPLAINTS OF WEAKNESS
OF UPPER AND LOWER LEFT
EXTREMITIES AND ALTERED
SPEECH. ACCORDING THE THE
SUBJECT, HE WAS FINE THE
NIGHT BEFORE BUT WHEN HE
WOKE UP, HE FELT
TINGLINGUPPER/LOWER
EXTREMITIES ALONG WITH
WEAKNESS AND HAD
DIFFICULTY SPEAKING. ON
ARRIVAL TO THE ER, MR
STROKE PROTOCOL WAS
IMPLEMENTED. DUE TO THE
TIMELINES, THE SUBJECT WAS
OUTSIDE OF THE
INTERVENTION WINDOW; HE
WAS ADMITTED TO
NEUROLOGY FOR FURTHER
MANAGEMENT. LAB SAMPLES
WERE COLLECTED; IMAGING
INCLUDED MRA HEAD AND
NECK; CHEST X-RAY;
FLUOROSCOPIC BARIUM
SWALLOW; TRANSTHORACIC
ECHOCARDIOGRAM. RESULTS
OF MRI HEAD: VASCULATURE:
STENOSIS AT THE LEFT
POSTERIOR CEREBRAL
ARTERY ORIGIN. MRI OF NECK:
MILD PLAQUE OF THE
PROXIMAL RIGHT AND LEFT

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

INTERNAL CAROTID ARTERIES
MRI OF THE BRAIN: THERE IS
DIFFUSION RESTRICTION
WITHIN THE PONS
BILATERALLY BUT MORE
PROMINENT THE RIGHT OF
MIDLINE. THERE IS NO
ABNORMAL FOCUS OF
SUSCEPTIBILITY. MINIMAL
PERIVENTRICULAR AND
SUBCORTICAL WHITE MATTER
T2 HYPERINTENSE SIGNAL
NOTED WITHOUT MASS
EFFECT. FLUOROSCOPIC
BARIUM SWALLOW: FINDINGS
WERE MULTIPLE EPISODES OF
DEEP PENETRATION. THERE IS
FLASH PENETRATION ON
ALMOST ALL SWALLOWS WITH
ALL CONSISTENCIES EXCEPT
FOR THE SOLID BOLUS. CHEST
X-RAY: FINDINGS REVEALED
HEART IS NORMAL IN SIZE; NO
INFILTRATE, PNEUMOTHORAX
OR EFFUSION; THE
MEDIASTINUM AND OSSEOUS
STRUCTURES ARE NORMAL.
TRANSTHORACIC
ECHOCARDIOGRAM: FINDINGS
ARE LEFT VENTRICLE CAVITY
SIZE IS NORMAL, EF 60-65%.
DOPPLER PARAMETERS ARE
CONSISTENT WITH ABNORMAL
LEFT VENTRICULAR
RELAXATION AND NORMAL

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

FILLING PRESSURE (GRADE 1
DIASTOLIC DYSFUNCTION).
LEFT ATRIUM: NORMAL IN SIZE
ATRIAL SEPTUM: THERE IS NO
RIGHT-TO-LEFT ATRIAL LEVEL
SHUNT SEEN WITH AGITATED
SALINE CONTRAST STUDY.
PULMONARY ARTERIES:
UNABLE TO ACCURATELY
ASSESS SYSTOLIC PRESSURE
DUE TO INSUFFICIENT
TRICUSPID REGURGITATION
JET. NO HEMODYNAMICALLY
SIGNIFICANT VALVULAR
REGURGITATION OR STENOSIS
IDENTIFIED.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

AEID	
Adverse event	RESTLESS LEG SYNDROME
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)	30 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

AEID	
Adverse event	STENOSIS, LEFT POSTERIOR CEREBRAL ARTERY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THIS EVENT WAS A FINDING NOTED ON THE MAGNETIC RESONANCE IMAGING REPORT DATED 22MAR2021. NO FURTHER REMARKS ARE FOUND REGARDING THE EVENT.

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Apr 2021 16:34:33

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Apr 2021 16:34:33

Generated On: 11 Jun 2021 15:10:15

AEID	
Adverse event	LEFT VENTRICULAR HYPERTROPHY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Apr 2021 16:34:33

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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	True
Concomitant Medication	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 16:05:55

Generated On: 11 Jun 2021 15:10:15

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication LOSARTAN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication VERAPAMIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication METFORMIN ER

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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 FEB 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication NOVOLIN R

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 MAR 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication NOVOLIN N

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPEDEMIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	18 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	18 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication LOPERAMIDE

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL SYNDROME

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION (WORSENING OF) AE

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	19 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 MAR 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"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 325

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	16 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 24 MAR 2021		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication BUTYRIC ACID

Prophylaxis Yes ☐
No ☒

Indication IBS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

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

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	24 MAR 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"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	31 MAR 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 300

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	30 MAR 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"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE PONTINE INFARCT

Dose per administration 300

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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 checked="" 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)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication ACUTE PONTINE INFARCT

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 MAR 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"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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EAB) (1725)

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)		24 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 MAR 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"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

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EAB) (1725)

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 MAR 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"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	30 MAR 2021	
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"/>

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE PONTINE INFARCT,
POST CARE

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)		24 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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 checked="" 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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 25 MAR 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication LOSARTAN
POTASSIUM/HYDROCHLOROTH
IAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)		30 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

Name of Medication SITAGLIPTIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 20:51:20

Generated On: 11 Jun 2021 15:10:15

	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)		30 MAR 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"/>

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 16:06:01

Generated On: 11 Jun 2021 15:10:15

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 16:06:01

Generated On: 11 Jun 2021 15:10:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 MAR 2021	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
22 MAR 2021	MAGNETIC RESONANCE IMAGING	Adverse Event	
22 MAR 2021	X-RAY CHEST	Adverse Event	
23 MAR 2021	FLUOROSCOPIC BARIUM SWALLOW	Adverse Event	
22 MAR 2021	ECHOCARDIOGRAM	Adverse Event	

US3912046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 15:10:15

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 ☐

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 13:51:35

Generated On: 11 Jun 2021 15:10:15

SAEID	USA-US211-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input 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)	5

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 13:51:35

Generated On: 11 Jun 2021 15:10:15

SAEID	USA-US211-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 14:45
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

US3912046

Folder: SAE-USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 13:51:35

Generated On: 11 Jun 2021 15:10:15

SAEID	USA-US211-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	05/APR/2021 12:35
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

US3912046

Folder: SAE-USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 13:51:35

Generated On: 11 Jun 2021 15:10:15

SAEID	USA-US211-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	06/APR/2021 09:41
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

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 13:51:35

Generated On: 11 Jun 2021 15:10:15

SAEID	USA-US211-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 12:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Apr 2021 13:51:35

Generated On: 11 Jun 2021 15:10:15

SAEID	USA-US211-2021-MRNA-1273-P301000003
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 checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	13/APR/2021 06:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3912046 (Prod: Synexus - Optimal Research - Austin)

US3912046

Form: Participant Creation

Generated On: 11 Jun 2021 15:10:15

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'US3912046'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:29:45

US3912046

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	31 Aug 2020 18:33:04
	(b) (4)	

US3912046

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '31 AUG 2020'	RWS_ENDPOINT	31 Aug 2020 15:29:46
	ENDPOINT (b) (4)	

US3912046

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	31 Aug 2020 18:33:04
	(b) (4)	

US3912046

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'SCRN'	System	31 Aug 2020 18:33:04

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered (b) (6) 1961'	RWS_ENDPOINT	31 Aug 2020 15:29:47
	ENDPOINT (b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '59'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'YEARS'	System	03 Sep 2020 12:13:37

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '59'	System	31 Aug 2020 18:34:35

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Male (M)'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'I'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:10:15

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Amy Collins (b) (4)	03 Sep 2020 12:13:37
	(b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '31 Aug 2020'	Tina Rountree (b) (4)	31 Aug 2020 18:34:35
	(b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Aug 2020'	System	31 Aug 2020 18:34:35

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '2020'	System	31 Aug 2020 18:34:35

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Amendment 3 (3)'	Tina Rountree (b) (4)	31 Aug 2020 18:34:35
	(b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	31 Aug 2020 18:34:35
	(b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	31 Aug 2020 18:34:35
	(b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	31 Aug 2020 18:34:35
	(b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	31 Aug 2020 18:34:35
	(b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	RWS_ENDPOINT	31 Aug 2020 15:29:46
	ENDPOINT (b) (4)	

US3912046

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:10:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'I'	System	31 Aug 2020 18:34:43

US3912046

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	31 Aug 2020 18:34:43
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History Summary

Generated On: 11 Jun 2021 15:10:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:08:50
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(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)	06 Sep 2020 18:10:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:10:33
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 18:09:43
User entered 'Hypertension'	Tina Rountree (b) (4)	06 Sep 2020 18:09:10
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'un UNK 2012'	Tina Rountree (b) (4)	06 Sep 2020 18:09:10
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:09:10
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:09:10
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:09:10
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:09:10
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Jan 2012'	System	06 Sep 2020 18:09:10

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '2012'	System	06 Sep 2020 18:09:10

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:09:10

US3912046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:09:10

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:10:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:10:33
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 18:09:44
User entered 'Type II Diabetes'	Tina Rountree (b) (4)	06 Sep 2020 18:09:34
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'un UNK 2014'	Tina Rountree (b) (4)	06 Sep 2020 18:09:34
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:09:34
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:09:34
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:09:34
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:09:34
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Jan 2014'	System	06 Sep 2020 18:09:34

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '2014'	System	06 Sep 2020 18:09:34

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:09:34

US3912046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:09:34

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:11:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:11:34
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 18:10:44
User entered 'Hyperlipedemia'	Tina Rountree (b) (4)	06 Sep 2020 18:09:52
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'un UNK 1987'	Tina Rountree (b) (4)	06 Sep 2020 18:09:52
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:09:52
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:09:52
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:09:52
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:09:52
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Jan 1987'	System	06 Sep 2020 18:09:52

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '1987'	System	06 Sep 2020 18:09:52

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:09:52

US3912046

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:09:52

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:11:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:11:34
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 18:10:46
User entered 'Irritable Bowel Syndrome'	Tina Rountree (b) (4)	06 Sep 2020 18:10:13
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'un UNK 1997'	Tina Rountree (b) (4)	06 Sep 2020 18:10:13
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:10:13
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:10:13
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:10:13
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:10:13
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Jan 1997'	System	06 Sep 2020 18:10:13

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '1997'	System	06 Sep 2020 18:10:13

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:10:13

US3912046

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:10:13

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Developmental disorders NEC, HLT: Pervasive developmental disorders NEC, PT: Autism spectrum disorder, LLT: Asperger's syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:12:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:12:34
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 18:11:47
User entered 'Aspergers Syndrome'	Tina Rountree (b) (4)	06 Sep 2020 18:10:47
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'un UNK 2015'	Tina Rountree (b) (4)	06 Sep 2020 18:10:47
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:10:47
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:10:47
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:10:47
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:10:47
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Jan 2015'	System	06 Sep 2020 18:10:47

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '2015'	System	06 Sep 2020 18:10:47

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:10:47

US3912046

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:10:47

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:12:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:12:34
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 18:11:47
User entered 'Erectile Dysfunction'	Tina Rountree (b) (4)	06 Sep 2020 18:11:08
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'un UNK 2014'	Tina Rountree (b) (4)	06 Sep 2020 18:11:08
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:11:08
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:11:08
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:11:08
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:11:08
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Jan 2014'	System	06 Sep 2020 18:11:08

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '2014'	System	06 Sep 2020 18:11:08

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:11:08

US3912046

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:11:08

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 05:28:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Sep 2020 05:28:50
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 18:11:47
User entered 'Diabetic Neuropathy - Bilateral feet'	Tina Rountree (b) (4)	06 Sep 2020 18:11:33
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'un UNK 2017'	Tina Rountree (b) (4)	06 Sep 2020 18:11:33
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:11:33
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:11:33
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:11:33
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:11:33
	(b) (4)	

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'Jan 2017'	System	06 Sep 2020 18:11:33

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '2017'	System	06 Sep 2020 18:11:33

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:11:33

US3912046

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	06 Sep 2020 18:11:33

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.		12 Apr 2021 15:57:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:56:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:56:02
Data point term sent to Coder	System	12 Apr 2021 13:55:26
User entered 'obesity'	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.		12 Apr 2021 15:57:49
User entered empty.	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.		12 Apr 2021 15:57:49
User entered 'I'	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.		12 Apr 2021 15:57:49
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.		12 Apr 2021 15:57:49
User entered empty.	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.		12 Apr 2021 15:57:49
User entered '0'	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Medical History (8)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	12 Apr 2021 13:54:30

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '31 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '10:41'	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '31 Aug 2020 10:41'	System	06 Sep 2020 18:13:15

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '70' in	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	
DataPoint set to visible.	System	31 Aug 2020 18:34:43

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '231' lb	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	
DataPoint set to visible.	System	31 Aug 2020 18:34:43

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '33.21435'	System	06 Sep 2020 18:13:15
DataPoint set to visible.	System	31 Aug 2020 18:34:43

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'kg/m2'	System	06 Sep 2020 18:13:15
DataPoint set to visible.	System	31 Aug 2020 18:34:43

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'bpm'	System	06 Sep 2020 18:13:15

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'breaths/min'	System	06 Sep 2020 18:13:15

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'mmHg'	System	06 Sep 2020 18:13:15

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:13:15
	(b) (4)	

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'mmHg'	System	06 Sep 2020 18:13:15

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46

US3912046

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46

US3912046

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:13:29
	(b) (4)	

US3912046

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '31 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:13:29
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

[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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

[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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

[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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'I'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:10:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Public transit 3 times per week'	Tina Rountree (b) (4)	06 Sep 2020 18:14:28
	(b) (4)	

US3912046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Tina Rountree (b) (4)	31 Aug 2020 18:35:02

US3912046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '31 Aug 2020'	Tina Rountree (b) (4)	31 Aug 2020 18:35:02

US3912046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	31 Aug 2020 18:35:02

US3912046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'VISIT1'	System	31 Aug 2020 18:35:02

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:34:25

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '145280'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:34:25

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:34:25

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
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) (4), (b) (6)	08 Sep 2020 07:52:21
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Data entered' (Site from DM).	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:15:18
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:15:04
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 14:55:43

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:15:04

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:15:04

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:15:04

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:15:04

US3912046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	Mia Rountree (b) (4)	26 Oct 2020 19:05:36
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:43:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:43:17

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User accepted default value 'Pre-Dose (PREDOSE)'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '31 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '10:41'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '31 Aug 2020 10:41'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '36.7' C	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Oral (Oral)'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '69'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'bpm'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '14'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'breaths/min'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '130'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'mmHg'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '82'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'mmHg'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered missing code ND - Not Done.	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User accepted default value 'Post-Dose (POSTDOSE)'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '31 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Sep 2020 18:21:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Sep 2020 18:21:32
User entered '14:05' reason for change: Data Entry Error	Tina Rountree (b) (4)	06 Sep 2020 18:21:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Sep 2020 18:21:20
User entered empty.	System	06 Sep 2020 18:21:20
	Tina Rountree (b) (4)	06 Sep 2020 18:21:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '31 Aug 2020 14:05'	System	06 Sep 2020 18:21:32
User entered empty.	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '36.6' C	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Oral (Oral)'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '73'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'bpm'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM). Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:44:08
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4)	26 Oct 2020 19:05:24
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 03:30:23
User entered '18'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'breaths/min'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '114'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'mmHg'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '71'	Tina Rountree (b) (4)	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'mmHg'	System	06 Sep 2020 18:21:20

US3912046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:21:39

US3912046

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:21:39

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '31 Aug 2020'	Tina Rountree (b) (4)	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '13:22'	Tina Rountree (b) (4)	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '31 Aug 2020 13:22'	System	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4)	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'ONCE'	System	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 18:36:08

US3912046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:22:17

US3912046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '31 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:22:17

US3912046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '12:11'	Tina Rountree (b) (4)	06 Sep 2020 18:22:17

US3912046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '31 Aug 2020 12:11'	System	06 Sep 2020 18:22:17

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 15:10:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '31 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tina Rountree (b) (4)	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '12:16'	Tina Rountree (b) (4)	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '31 Aug 2020 12:16'	System	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tina Rountree (b) (4)	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered empty.	System	06 Sep 2020 18:22:38

US3912046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:22:44

US3912046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	06 Sep 2020 18:22:44

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:10:14', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd30eb094-b9bc-47f1-baf7-ccb0bf3fbbea' User entered 'Yes (Y)'	System	31 Aug 2020 19:23:07
	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:10:23', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd30eb094-b9bc-47f1-baf7-ccb0bf3fbbea' User entered '97.9'	System	31 Aug 2020 19:23:07
	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:10:28', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd30eb094-b9bc-47f1-baf7-ccb0bf3fbbea'	System	31 Aug 2020 19:23:07
User entered 'No (N)'	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:10:33', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd30eb094-b9bc-47f1-baf7-ccb0bf3fbbea'	System	31 Aug 2020 19:23:07
User entered '31 Aug 2020 14:10'	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 13:42'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 16:12'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T23:23:59', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd957a94e-5e8a-4431-8ea2-b9f8e7a24702'	System	01 Sep 2020 04:24:08
User entered 'No (N)'	System	01 Sep 2020 04:24:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T23:24:02', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd957a94e-5e8a-4431-8ea2-b9f8e7a24702'	System	01 Sep 2020 04:24:08
User entered 'No (N)'	System	01 Sep 2020 04:24:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T23:24:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd957a94e-5e8a-4431-8ea2-b9f8e7a24702'	System	01 Sep 2020 04:24:08
User entered '31 Aug 2020 23:24'	System	01 Sep 2020 04:24:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 17:07'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 2'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:20:21', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f5f5c3d0-ee51-4432-84e7-577708f61c80' User entered 'Yes (Y)'	System	01 Sep 2020 21:20:42
	System	01 Sep 2020 21:20:42

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:20:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f5f5c3d0-ee51-4432-84e7-577708f61c80' User entered '97.7'	System	01 Sep 2020 21:20:42
	System	01 Sep 2020 21:20:42

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:20:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f5f5c3d0-ee51-4432-84e7-577708f61c80'	System	01 Sep 2020 21:20:42
User entered 'No (N)'	System	01 Sep 2020 21:20:42

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:20:40', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f5f5c3d0-ee51-4432-84e7-577708f61c80'	System	01 Sep 2020 21:20:42
User entered '01 Sep 2020 16:20'	System	01 Sep 2020 21:20:42

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 3'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:45:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '70c84a12-a583-4372-925c-710cfed0f0cc'	System	02 Sep 2020 18:45:58
User entered 'Yes (Y)'	System	02 Sep 2020 18:45:58

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:45:44', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '70c84a12-a583-4372-925c-710cfed0f0cc' User entered '98.5'	System	02 Sep 2020 18:45:58
	System	02 Sep 2020 18:45:58

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:45:48', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '70c84a12-a583-4372-925c-710cfed0f0cc'	System	02 Sep 2020 18:45:58
User entered 'No (N)'	System	02 Sep 2020 18:45:58

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:45:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '70c84a12-a583-4372-925c-710cfed0f0cc'	System	02 Sep 2020 18:45:58
User entered '02 Sep 2020 13:45'	System	02 Sep 2020 18:45:58

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 4'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:13', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'da27c555-8cc8-46a8-8b8d-5dc5964116ad' User entered 'Yes (Y)'	System	03 Sep 2020 18:34:37
	System	03 Sep 2020 18:34:37

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:22', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'da27c555-8cc8-46a8-8b8d-5dc5964116ad' User entered '98.6'	System	03 Sep 2020 18:34:37
	System	03 Sep 2020 18:34:37

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:26', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'da27c555-8cc8-46a8-8b8d-5dc5964116ad' User entered 'No (N)'	System	03 Sep 2020 18:34:37
	System	03 Sep 2020 18:34:37

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:33', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'da27c555-8cc8-46a8-8b8d-5dc5964116ad' User entered '03 Sep 2020 13:34'	System	03 Sep 2020 18:34:37
	System	03 Sep 2020 18:34:37

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 5'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:45:43', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f1756f1c-7d23-4756-9256-2ec27b3ca103'	System	04 Sep 2020 18:46:08
User entered 'Yes (Y)'	System	04 Sep 2020 18:46:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:45:55', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f1756f1c-7d23-4756-9256-2ec27b3ca103'	System	04 Sep 2020 18:46:08
User entered '97.8'	System	04 Sep 2020 18:46:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:45:59', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f1756f1c-7d23-4756-9256-2ec27b3ca103'	System	04 Sep 2020 18:46:08
User entered 'No (N)'	System	04 Sep 2020 18:46:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f1756f1c-7d23-4756-9256-2ec27b3ca103'	System	04 Sep 2020 18:46:08
User entered '04 Sep 2020 13:46'	System	04 Sep 2020 18:46:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 6'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '81a2a52b-64f3-4579-8ad4-8d34c6d60c28' User entered 'Yes (Y)'	System	06 Sep 2020 12:03:24
	System	06 Sep 2020 12:03:24

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:12', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '81a2a52b-64f3-4579-8ad4-8d34c6d60c28' User entered '98.6'	System	06 Sep 2020 12:03:24
	System	06 Sep 2020 12:03:24

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:17', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '81a2a52b-64f3-4579-8ad4-8d34c6d60c28'	System	06 Sep 2020 12:03:24
User entered 'No (N)'	System	06 Sep 2020 12:03:24

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:22', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '81a2a52b-64f3-4579-8ad4-8d34c6d60c28' User entered '06 Sep 2020 07:03'	System	06 Sep 2020 12:03:24
	System	06 Sep 2020 12:03:24

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 7'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '66e3dfdb-7af1-4f2b-b99d-37075176728d' User entered 'Yes (Y)'	System	06 Sep 2020 21:35:15
	System	06 Sep 2020 21:35:15

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '66e3dfdb-7af1-4f2b-b99d-37075176728d' User entered '99.4'	System	06 Sep 2020 21:35:15
	System	06 Sep 2020 21:35:15

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '66e3dfdb-7af1-4f2b-b99d-37075176728d' User entered 'No (N)'	System	06 Sep 2020 21:35:15
	System	06 Sep 2020 21:35:15

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:14', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '66e3dfdb-7af1-4f2b-b99d-37075176728d' User entered '06 Sep 2020 16:35'	System	06 Sep 2020 21:35:15
	System	06 Sep 2020 21:35:15

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:10:53', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b1cf1f9a-7937-4ec0-bfc6-dae49a3ca806'	System	31 Aug 2020 19:23:07
User entered 'None (1)'	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:11:25', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b1cf1f9a-7937-4ec0-bfc6-dae49a3ca806'	System	31 Aug 2020 19:23:07
User entered 'No (N)'	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:11:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b1cf1f9a-7937-4ec0-bfc6-dae49a3ca806'	System	31 Aug 2020 19:23:07
User entered 'No (N)'	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:11:33', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b1cf1f9a-7937-4ec0-bfc6-dae49a3ca806'	System	31 Aug 2020 19:23:07
User entered 'None (1)'	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:11:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b1cf1f9a-7937-4ec0-bfc6-dae49a3ca806'	System	31 Aug 2020 19:23:07
User entered '31 Aug 2020 14:11'	System	31 Aug 2020 19:23:07

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 13:42'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 16:12'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '185e6357-11cb-41d3-9efd-7fea5512ae42'	System	01 Sep 2020 02:07:11
User entered 'None (1)'	System	01 Sep 2020 02:07:11

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:55', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '185e6357-11cb-41d3-9efd-7fea5512ae42'	System	01 Sep 2020 02:07:11
User entered 'No (N)'	System	01 Sep 2020 02:07:11

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:58', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '185e6357-11cb-41d3-9efd-7fea5512ae42'	System	01 Sep 2020 02:07:11
User entered 'No (N)'	System	01 Sep 2020 02:07:11

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:07:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '185e6357-11cb-41d3-9efd-7fea5512ae42'	System	01 Sep 2020 02:07:11
User entered 'None (1)'	System	01 Sep 2020 02:07:11

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:07:09', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '185e6357-11cb-41d3-9efd-7fea5512ae42'	System	01 Sep 2020 02:07:11
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 02:07:11

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 17:07'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 2'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:20:59', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9ef3d4bc-febb-4be2-a4b9-dff3f3b52e5f' User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 21:21:29
	System	01 Sep 2020 21:21:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:03', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9ef3d4bc-febb-4be2-a4b9-dff3f3b52e5f' User entered 'Yes (Y)'	System	01 Sep 2020 21:21:29
	System	01 Sep 2020 21:21:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9ef3d4bc-febb-4be2-a4b9-dff3f3b52e5f' User entered '2'	System	01 Sep 2020 21:21:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:13', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9ef3d4bc-febb-4be2-a4b9-dff3f3b52e5f' User entered 'No (N)'	System	01 Sep 2020 21:21:29
	System	01 Sep 2020 21:21:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:20', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9ef3d4bc-febb-4be2-a4b9-dff3f3b52e5f' User entered 'None (1)'	System	01 Sep 2020 21:21:29
	System	01 Sep 2020 21:21:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9ef3d4bc-febb-4be2-a4b9-dff3f3b52e5f' User entered '01 Sep 2020 16:21'	System	01 Sep 2020 21:21:29
	System	01 Sep 2020 21:21:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 3'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:01', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f8f64b3e-0e95-4c66-9e62-7b2f9c319c98'	System	02 Sep 2020 18:46:42
User entered 'None (1)'	System	02 Sep 2020 18:46:42

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:30', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f8f64b3e-0e95-4c66-9e62-7b2f9c319c98'	System	02 Sep 2020 18:46:42
User entered 'No (N)'	System	02 Sep 2020 18:46:42

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:17', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f8f64b3e-0e95-4c66-9e62-7b2f9c319c98'	System	02 Sep 2020 18:46:42
User entered 'No (N)'	System	02 Sep 2020 18:46:42

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:36', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f8f64b3e-0e95-4c66-9e62-7b2f9c319c98'	System	02 Sep 2020 18:46:42
User entered 'None (1)'	System	02 Sep 2020 18:46:42

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:39', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'f8f64b3e-0e95-4c66-9e62-7b2f9c319c98'	System	02 Sep 2020 18:46:42
User entered '02 Sep 2020 13:46'	System	02 Sep 2020 18:46:42

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 4'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4ed90b9b-6d6d-4e76-9ff3-970c593586cf' User entered 'None (1)'	System	03 Sep 2020 18:34:57
	System	03 Sep 2020 18:34:57

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:42', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4ed90b9b-6d6d-4e76-9ff3-970c593586cf' User entered 'No (N)'	System	03 Sep 2020 18:34:57
	System	03 Sep 2020 18:34:57

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:44', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4ed90b9b-6d6d-4e76-9ff3-970c593586cf' User entered 'No (N)'	System	03 Sep 2020 18:34:57
	System	03 Sep 2020 18:34:57

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4ed90b9b-6d6d-4e76-9ff3-970c593586cf' User entered 'None (1)'	System	03 Sep 2020 18:34:57
	System	03 Sep 2020 18:34:57

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:54', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4ed90b9b-6d6d-4e76-9ff3-970c593586cf' User entered '03 Sep 2020 13:34'	System	03 Sep 2020 18:34:57
	System	03 Sep 2020 18:34:57

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 5'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:09', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e5c8edd8-1953-41ea-abd9-ffc677a8bf5b'	System	04 Sep 2020 18:46:29
User entered 'None (1)'	System	04 Sep 2020 18:46:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:13', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e5c8edd8-1953-41ea-abd9-ffc677a8bf5b' User entered 'No (N)'	System	04 Sep 2020 18:46:29
	System	04 Sep 2020 18:46:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:17', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e5c8edd8-1953-41ea-abd9-ffc677a8bf5b'	System	04 Sep 2020 18:46:29
User entered 'No (N)'	System	04 Sep 2020 18:46:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e5c8edd8-1953-41ea-abd9-ffc677a8bf5b'	System	04 Sep 2020 18:46:29
User entered 'None (1)'	System	04 Sep 2020 18:46:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:27', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e5c8edd8-1953-41ea-abd9-ffc677a8bf5b' User entered '04 Sep 2020 13:46'	System	04 Sep 2020 18:46:29
	System	04 Sep 2020 18:46:29

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 6'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1787d4cd-418e-4844-a249-856ca0ba3781'	System	06 Sep 2020 12:03:48
User entered 'None (1)'	System	06 Sep 2020 12:03:48

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:33', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1787d4cd-418e-4844-a249-856ca0ba3781' User entered 'No (N)'	System	06 Sep 2020 12:03:48
	System	06 Sep 2020 12:03:48

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1787d4cd-418e-4844-a249-856ca0ba3781' User entered 'No (N)'	System	06 Sep 2020 12:03:48
	System	06 Sep 2020 12:03:48

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:43', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1787d4cd-418e-4844-a249-856ca0ba3781' User entered 'None (1)'	System	06 Sep 2020 12:03:48
	System	06 Sep 2020 12:03:48

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:46', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1787d4cd-418e-4844-a249-856ca0ba3781' User entered '06 Sep 2020 07:03'	System	06 Sep 2020 12:03:48
	System	06 Sep 2020 12:03:48

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 7'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:19', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '8f7c9721-9c09-4536-b3d4-612b1c07ff2b' User entered 'None (1)'	System	06 Sep 2020 21:35:37
	System	06 Sep 2020 21:35:37

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:23', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '8f7c9721-9c09-4536-b3d4-612b1c07ff2b' User entered 'No (N)'	System	06 Sep 2020 21:35:37
	System	06 Sep 2020 21:35:37

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:28', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '8f7c9721-9c09-4536-b3d4-612b1c07ff2b' User entered 'No (N)'	System	06 Sep 2020 21:35:37
	System	06 Sep 2020 21:35:37

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '8f7c9721-9c09-4536-b3d4-612b1c07ff2b' User entered 'None (1)'	System	06 Sep 2020 21:35:37
	System	06 Sep 2020 21:35:37

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:34', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '8f7c9721-9c09-4536-b3d4-612b1c07ff2b' User entered '06 Sep 2020 16:35'	System	06 Sep 2020 21:35:37
	System	06 Sep 2020 21:35:37

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:11:45', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697' User entered 'None (0)'	System	31 Aug 2020 19:23:12
	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:11:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697'	System	31 Aug 2020 19:23:12
User entered 'No interference with activity (1)'	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:12:07', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697' User entered 'None (0)'	System	31 Aug 2020 19:23:12
	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:12:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697' User entered 'None (0)'	System	31 Aug 2020 19:23:12
	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:12:13', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697' User entered 'None (0)'	System	31 Aug 2020 19:23:12
	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:12:15', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697' User entered 'None (0)'	System	31 Aug 2020 19:23:12
	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:12:21', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697'	System	31 Aug 2020 19:23:12
User entered 'No (N)'	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T14:12:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22a45a0a-12e8-4131-87b7-fd1356867697'	System	31 Aug 2020 19:23:12
User entered '31 Aug 2020 14:12'	System	31 Aug 2020 19:23:12

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 13:42'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 16:12'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:05:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796' User entered 'None (0)'	System	01 Sep 2020 02:06:46
	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796'	System	01 Sep 2020 02:06:46
User entered 'No interference with activity (1)'	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:07', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796' User entered 'None (0)'	System	01 Sep 2020 02:06:46
	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796' User entered 'None (0)'	System	01 Sep 2020 02:06:46
	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:12', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796' User entered 'None (0)'	System	01 Sep 2020 02:06:46
	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:15', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796' User entered 'None (0)'	System	01 Sep 2020 02:06:46
	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:33', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796'	System	01 Sep 2020 02:06:46
User entered 'Yes (Y)'	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-08-31T21:06:43', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'c1340664-68ba-4062-933f-ac49efffd796'	System	01 Sep 2020 02:06:46
User entered '31 Aug 2020 21:06'	System	01 Sep 2020 02:06:46

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '31 Aug 2020 17:07'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 2'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered 'None (0)'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:35', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered 'None (0)'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered 'None (0)'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:40', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered 'None (0)'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:42', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered 'None (0)'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:45', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered 'None (0)'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:48', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered 'No (N)'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-01T16:21:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b12443b-7dd4-4b02-96d8-10952f40278e' User entered '01 Sep 2020 16:21'	System	01 Sep 2020 21:21:57
	System	01 Sep 2020 21:21:57

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 3'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:44', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c' User entered 'None (0)'	System	02 Sep 2020 18:47:14
	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:54', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c' User entered 'None (0)'	System	02 Sep 2020 18:47:14
	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:46:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c' User entered 'None (0)'	System	02 Sep 2020 18:47:14
	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:47:01', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c'	System	02 Sep 2020 18:47:14
User entered 'No interference with activity (1)'	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:47:04', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c' User entered 'None (0)'	System	02 Sep 2020 18:47:14
	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:47:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c' User entered 'None (0)'	System	02 Sep 2020 18:47:14
	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:47:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c' User entered 'No (N)'	System	02 Sep 2020 18:47:14
	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-02T13:47:12', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '40be2e12-11fa-4b4a-ae1a-c0c92a34804c' User entered '02 Sep 2020 13:47'	System	02 Sep 2020 18:47:14
	System	02 Sep 2020 18:47:14

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 4'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:34:59', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered 'None (0)'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:35:02', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered 'None (0)'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:35:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered 'None (0)'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:35:08', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered 'None (0)'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:35:12', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered 'None (0)'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:35:14', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered 'None (0)'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:35:17', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered 'No (N)'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-03T13:35:20', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b9058852-2f8b-46d5-98e9-ca5f1937a6f1' User entered '03 Sep 2020 13:35'	System	03 Sep 2020 18:35:21
	System	03 Sep 2020 18:35:21

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 5'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:47', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered 'None (0)'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:49', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered 'None (0)'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered 'None (0)'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:54', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered 'None (0)'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered 'None (0)'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:46:58', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered 'None (0)'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:47:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered 'No (N)'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-04T13:47:07', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '76824592-b9ba-4ba2-b778-b0698b76d024' User entered '04 Sep 2020 13:47'	System	04 Sep 2020 18:47:11
	System	04 Sep 2020 18:47:11

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 6'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:50', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered 'None (0)'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered 'None (0)'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:03:59', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered 'None (0)'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:04:03', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered 'None (0)'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:04:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered 'None (0)'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:04:08', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered 'None (0)'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:04:12', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered 'No (N)'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T07:04:15', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '1a699499-c35b-4eb4-9b50-e0dfa0a33284' User entered '06 Sep 2020 07:04'	System	06 Sep 2020 12:04:18
	System	06 Sep 2020 12:04:18

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 7'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:41', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a' User entered 'None (0)'	System	06 Sep 2020 21:36:04
	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:45', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a' User entered 'None (0)'	System	06 Sep 2020 21:36:04
	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:47', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a' User entered 'None (0)'	System	06 Sep 2020 21:36:04
	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:49', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a' User entered 'None (0)'	System	06 Sep 2020 21:36:04
	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a' User entered 'None (0)'	System	06 Sep 2020 21:36:04
	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:35:53', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a' User entered 'None (0)'	System	06 Sep 2020 21:36:04
	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:36:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a' User entered 'No (N)'	System	06 Sep 2020 21:36:04
	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-06T16:36:03', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '25b49109-272b-472a-8b18-5170dc83b68a'	System	06 Sep 2020 21:36:04
User entered '06 Sep 2020 16:36'	System	06 Sep 2020 21:36:04

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:36:08

US3912046

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	08 Sep 2020 23:52:57

US3912046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '8 Sep 2020'	Tina Rountree (b) (4)	08 Sep 2020 23:52:57

US3912046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	Tina Rountree (b) (4)	08 Sep 2020 23:52:57

US3912046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	08 Sep 2020 23:52:57

US3912046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	08 Sep 2020 23:52:42

US3912046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	08 Sep 2020 23:52:42

US3912046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:45:39

US3912046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 21:45:39

US3912046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 21:45:39

US3912046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:45:39

US3912046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 21:51:17

US3912046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	15 Sep 2020 21:51:17

US3912046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:33:45

US3912046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:33:45

US3912046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 15:33:45

US3912046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:33:45

US3912046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:33:49

US3912046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	22 Sep 2020 15:33:49

US3912046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Sep 2020 16:16:14

US3912046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '28 Sep 2020'	Tina Rountree (b) (4)	28 Sep 2020 16:16:14

US3912046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	28 Sep 2020 16:16:14

US3912046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'VISIT2'	System	28 Sep 2020 16:16:14

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User accepted default value 'Pre-Dose (PREDOSE)'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15
	(b) (4)	

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '28 Sep 2020'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '09:38'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered '28 Sep 2020 09:38'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '36.7' C	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '86'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'bpm'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM). Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:55:17
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4)	26 Oct 2020 19:07:08
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM). User entered '18'	(b) (4), (b) (6)	26 Oct 2020 13:44:16
	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'breaths/min'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '124'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'mmHg'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '73'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'mmHg'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User accepted default value 'Post-Dose (POSTDOSE)'	Mia Rountree (b) (4) (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '28 Sep 2020'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '11:52'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered '28 Sep 2020 11:52'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '36.8' C	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '91'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'bpm'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '16'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'breaths/min'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '128'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'mmHg'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '75'	Mia Rountree (b) (4)	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'mmHg'	System	16 Oct 2020 18:45:15

US3912046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Sep 2020 16:16:22

US3912046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '28 Sep 2020'	Tina Rountree (b) (4)	28 Sep 2020 16:16:22

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	(b) (4) Tina Rountree (b) (4)	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	Tina Rountree (b) (4)	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '28 Sep 2020'	Tina Rountree (b) (4)	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '11:07'	Tina Rountree (b) (4)	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '28 Sep 2020 11:07'	System	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4)	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'ONCE'	System	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 16:16:48

US3912046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Sep 2020 16:17:07

US3912046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '28 Sep 2020'	Tina Rountree (b) (4)	28 Sep 2020 16:17:07

US3912046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '10:04'	Tina Rountree (b) (4)	28 Sep 2020 16:17:07

US3912046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '28 Sep 2020 10:04'	System	28 Sep 2020 16:17:07

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 15:10:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '28 Sep 2020'	Tina Rountree (b) (4)	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tina Rountree (b) (4)	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '10:11'	Tina Rountree (b) (4)	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered '28 Sep 2020 10:11'	System	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tina Rountree (b) (4)	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'No (N)'	Tina Rountree (b) (4)	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	Tina Rountree (b) (4)	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered empty.	System	28 Sep 2020 16:17:20

US3912046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 22:34:25

US3912046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	06 Oct 2020 22:34:25

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:01:52', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b5feeb15-6a8c-44ce-b483-492aa93bc3e4'	System	28 Sep 2020 17:02:43
User entered 'Yes (Y)'	System	28 Sep 2020 17:02:43

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:02:01', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b5feeb15-6a8c-44ce-b483-492aa93bc3e4'	System	28 Sep 2020 17:02:43
User entered '98.2'	System	28 Sep 2020 17:02:43

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:02:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b5feeb15-6a8c-44ce-b483-492aa93bc3e4'	System	28 Sep 2020 17:02:43
User entered 'No (N)'	System	28 Sep 2020 17:02:43

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:02:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b5feeb15-6a8c-44ce-b483-492aa93bc3e4' User entered '28 Sep 2020 12:02'	System	28 Sep 2020 17:02:43
	System	28 Sep 2020 17:02:43

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 11:27'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 13:57'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:02', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b8b88d9a-89fc-4bb1-80f4-dde475897a10'	System	29 Sep 2020 15:56:18
User entered 'Yes (Y)'	System	29 Sep 2020 15:56:18

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:55:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b8b88d9a-89fc-4bb1-80f4-dde475897a10' User entered '98.3'	System	29 Sep 2020 15:56:18
	System	29 Sep 2020 15:56:18

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:55:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b8b88d9a-89fc-4bb1-80f4-dde475897a10'	System	29 Sep 2020 15:56:18
User entered 'No (N)'	System	29 Sep 2020 15:56:18

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:14', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b8b88d9a-89fc-4bb1-80f4-dde475897a10' User entered '29 Sep 2020 10:56'	System	29 Sep 2020 15:56:18
	System	29 Sep 2020 15:56:18

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 14:52'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 2'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:57:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '73cdbf23-74c0-41c5-a5a2-171a5e5d4abe' User entered 'Yes (Y)'	System	30 Sep 2020 09:57:59
	System	30 Sep 2020 09:57:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:57:44', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '73cdbf23-74c0-41c5-a5a2-171a5e5d4abe' User entered '98.4'	System	30 Sep 2020 09:57:59
	System	30 Sep 2020 09:57:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:57:50', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '73cdbf23-74c0-41c5-a5a2-171a5e5d4abe' User entered 'No (N)'	System	30 Sep 2020 09:57:59
	System	30 Sep 2020 09:57:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:57:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '73cdbf23-74c0-41c5-a5a2-171a5e5d4abe' User entered '30 Sep 2020 04:57'	System	30 Sep 2020 09:57:59
	System	30 Sep 2020 09:57:59

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 3'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:35:14', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '43fe8eed-4077-4104-a3a7-a1cb31684280' User entered 'Yes (Y)'	System	01 Oct 2020 12:35:46
	System	01 Oct 2020 12:35:46

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:35:20', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '43fe8eed-4077-4104-a3a7-a1cb31684280' User entered '98.6'	System	01 Oct 2020 12:35:46
	System	01 Oct 2020 12:35:46

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:35:36', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '43fe8eed-4077-4104-a3a7-a1cb31684280'	System	01 Oct 2020 12:35:46
User entered 'No (N)'	System	01 Oct 2020 12:35:46

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:35:43', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '43fe8eed-4077-4104-a3a7-a1cb31684280' User entered '01 Oct 2020 07:35'	System	01 Oct 2020 12:35:46
	System	01 Oct 2020 12:35:46

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 4'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T07:26:22', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'fa88fb02-6c77-48e1-885c-e8893615b7fb' User entered 'Yes (Y)'	System	02 Oct 2020 12:26:40
	System	02 Oct 2020 12:26:40

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T07:26:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'fa88fb02-6c77-48e1-885c-e8893615b7fb' User entered '95.6'	System	02 Oct 2020 12:26:40
	System	02 Oct 2020 12:26:40

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T07:26:34', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'fa88fb02-6c77-48e1-885c-e8893615b7fb' User entered 'No (N)'	System	02 Oct 2020 12:26:40
	System	02 Oct 2020 12:26:40

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T07:26:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'fa88fb02-6c77-48e1-885c-e8893615b7fb' User entered '02 Oct 2020 07:26'	System	02 Oct 2020 12:26:40
	System	02 Oct 2020 12:26:40

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 5'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:48:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e99a3958-40fe-4d3b-ae0-4d7deb227f2e' User entered 'Yes (Y)'	System	02 Oct 2020 23:48:44
	System	02 Oct 2020 23:48:44

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:48:34', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e99a3958-40fe-4d3b-ae0-4d7deb227f2e' User entered '98.2'	System	02 Oct 2020 23:48:44
	System	02 Oct 2020 23:48:44

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:48:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e99a3958-40fe-4d3b-ae0-4d7deb227f2e'	System	02 Oct 2020 23:48:44
User entered 'No (N)'	System	02 Oct 2020 23:48:44

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:48:41', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'e99a3958-40fe-4d3b-ae0-4d7deb227f2e'	System	02 Oct 2020 23:48:44
User entered '02 Oct 2020 18:48'	System	02 Oct 2020 23:48:44

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 6'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:56:39', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3961a096-5f36-4f81-a728-99c26a045146' User entered 'Yes (Y)'	System	03 Oct 2020 18:57:35
	System	03 Oct 2020 18:57:35

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:21', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3961a096-5f36-4f81-a728-99c26a045146' User entered '98.2'	System	03 Oct 2020 18:57:35
	System	03 Oct 2020 18:57:35

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:26', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3961a096-5f36-4f81-a728-99c26a045146'	System	03 Oct 2020 18:57:35
User entered 'No (N)'	System	03 Oct 2020 18:57:35

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:31', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3961a096-5f36-4f81-a728-99c26a045146' User entered '03 Oct 2020 13:57'	System	03 Oct 2020 18:57:35
	System	03 Oct 2020 18:57:35

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 7'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:00:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4b22b74c-a6f8-471b-b370-4671b77c60b1' User entered 'Yes (Y)'	System	04 Oct 2020 17:00:58
	System	04 Oct 2020 17:00:58

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:00:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4b22b74c-a6f8-471b-b370-4671b77c60b1' User entered '98.0'	System	04 Oct 2020 17:00:58
	System	04 Oct 2020 17:00:58

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:00:42', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4b22b74c-a6f8-471b-b370-4671b77c60b1' User entered 'No (N)'	System	04 Oct 2020 17:00:58
	System	04 Oct 2020 17:00:58

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:00:48', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '4b22b74c-a6f8-471b-b370-4671b77c60b1' User entered '04 Oct 2020 12:00'	System	04 Oct 2020 17:00:58
	System	04 Oct 2020 17:00:58

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:02:35', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2cf1e1b-dcc2-48f5-a6e7-edc1775f121d' User entered 'None (1)'	System	28 Sep 2020 17:03:40
	System	28 Sep 2020 17:03:40

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:02:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2cf1e1b-dcc2-48f5-a6e7-edc1775f121d'	System	28 Sep 2020 17:03:40
User entered 'Yes (Y)'	System	28 Sep 2020 17:03:40

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:02:55', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2cf1e1b-dcc2-48f5-a6e7-edc1775f121d' User entered '1'	System	28 Sep 2020 17:03:40
	System	28 Sep 2020 17:03:40

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:01', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2cf1e1b-dcc2-48f5-a6e7-edc1775f121d'	System	28 Sep 2020 17:03:40
User entered 'No (N)'	System	28 Sep 2020 17:03:40

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2cf1e1b-dcc2-48f5-a6e7-edc1775f121d'	System	28 Sep 2020 17:03:40
User entered 'None (1)'	System	28 Sep 2020 17:03:40

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:09', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2cf1e1b-dcc2-48f5-a6e7-edc1775f121d' User entered '28 Sep 2020 12:03'	System	28 Sep 2020 17:03:40
	System	28 Sep 2020 17:03:40

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 11:27'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 13:57'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:22', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cbcdf1f2-5565-4786-b13e-c9b1eedd89c4' User entered 'None (1)'	System	29 Sep 2020 15:56:52
	System	29 Sep 2020 15:56:52

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:28', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cbcdf1f2-5565-4786-b13e-c9b1eedd89c4'	System	29 Sep 2020 15:56:52
User entered 'No (N)'	System	29 Sep 2020 15:56:52

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:36', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cbcdf1f2-5565-4786-b13e-c9b1eedd89c4'	System	29 Sep 2020 15:56:52
User entered 'No (N)'	System	29 Sep 2020 15:56:52

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:44', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cbcdf1f2-5565-4786-b13e-c9b1eedd89c4' User entered 'None (1)'	System	29 Sep 2020 15:56:52
	System	29 Sep 2020 15:56:52

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:49', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cbcdf1f2-5565-4786-b13e-c9b1eedd89c4' User entered '29 Sep 2020 10:56'	System	29 Sep 2020 15:56:52
	System	29 Sep 2020 15:56:52

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 14:52'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 2'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:04', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7614a937-cab2-459e-b414-56dfe6d2acbd' User entered 'None (1)'	System	30 Sep 2020 09:58:35
	System	30 Sep 2020 09:58:35

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:13', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7614a937-cab2-459e-b414-56dfe6d2acbd' User entered 'No (N)'	System	30 Sep 2020 09:58:35
	System	30 Sep 2020 09:58:35

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

Is there any SWELLING/HARDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:17', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7614a937-cab2-459e-b414-56dfe6d2acbd' User entered 'No (N)'	System	30 Sep 2020 09:58:35
	System	30 Sep 2020 09:58:35

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:25', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7614a937-cab2-459e-b414-56dfe6d2acbd' User entered 'None (1)'	System	30 Sep 2020 09:58:35
	System	30 Sep 2020 09:58:35

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:33', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7614a937-cab2-459e-b414-56dfe6d2acbd' User entered '30 Sep 2020 04:58'	System	30 Sep 2020 09:58:35
	System	30 Sep 2020 09:58:35

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 3'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:35:50', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd9d31b74-465f-47ac-952a-112df8b5226b' User entered 'None (1)'	System	01 Oct 2020 12:36:28
	System	01 Oct 2020 12:36:28

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:35:58', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd9d31b74-465f-47ac-952a-112df8b5226b' User entered 'No (N)'	System	01 Oct 2020 12:36:28
	System	01 Oct 2020 12:36:28

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:07', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd9d31b74-465f-47ac-952a-112df8b5226b' User entered 'No (N)'	System	01 Oct 2020 12:36:28
	System	01 Oct 2020 12:36:28

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:19', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd9d31b74-465f-47ac-952a-112df8b5226b' User entered 'None (1)'	System	01 Oct 2020 12:36:28
	System	01 Oct 2020 12:36:28

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd9d31b74-465f-47ac-952a-112df8b5226b' User entered '01 Oct 2020 07:36'	System	01 Oct 2020 12:36:28
	System	01 Oct 2020 12:36:28

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 4'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:19', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7394bc0-af72-41af-8af9-685d7e18ad70'	System	01 Oct 2020 17:03:01
User entered 'None (1)'	System	01 Oct 2020 17:03:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:23', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7394bc0-af72-41af-8af9-685d7e18ad70'	System	01 Oct 2020 17:03:01
User entered 'No (N)'	System	01 Oct 2020 17:03:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:36', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7394bc0-af72-41af-8af9-685d7e18ad70'	System	01 Oct 2020 17:03:01
User entered 'No (N)'	System	01 Oct 2020 17:03:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:45', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7394bc0-af72-41af-8af9-685d7e18ad70'	System	01 Oct 2020 17:03:01
User entered 'None (1)'	System	01 Oct 2020 17:03:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:58', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7394bc0-af72-41af-8af9-685d7e18ad70' User entered '01 Oct 2020 12:01'	System	01 Oct 2020 17:03:01
	System	01 Oct 2020 17:03:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 5'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:48:46', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '055c1639-2c14-4972-8adb-077395514eea' User entered 'None (1)'	System	02 Oct 2020 23:49:09
	System	02 Oct 2020 23:49:09

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:48:54', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '055c1639-2c14-4972-8adb-077395514eea' User entered 'No (N)'	System	02 Oct 2020 23:49:09
	System	02 Oct 2020 23:49:09

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '055c1639-2c14-4972-8adb-077395514eea' User entered 'No (N)'	System	02 Oct 2020 23:49:09
	System	02 Oct 2020 23:49:09

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:05', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '055c1639-2c14-4972-8adb-077395514eea' User entered 'None (1)'	System	02 Oct 2020 23:49:09
	System	02 Oct 2020 23:49:09

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:08', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '055c1639-2c14-4972-8adb-077395514eea' User entered '02 Oct 2020 18:49'	System	02 Oct 2020 23:49:09
	System	02 Oct 2020 23:49:09

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 6'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:35', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '04b73233-085d-4ee8-880a-c54b11eb7e61' User entered 'None (1)'	System	03 Oct 2020 18:58:01
	System	03 Oct 2020 18:58:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:40', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '04b73233-085d-4ee8-880a-c54b11eb7e61' User entered 'No (N)'	System	03 Oct 2020 18:58:01
	System	03 Oct 2020 18:58:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:43', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '04b73233-085d-4ee8-880a-c54b11eb7e61' User entered 'No (N)'	System	03 Oct 2020 18:58:01
	System	03 Oct 2020 18:58:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:49', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '04b73233-085d-4ee8-880a-c54b11eb7e61' User entered 'None (1)'	System	03 Oct 2020 18:58:01
	System	03 Oct 2020 18:58:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:57:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '04b73233-085d-4ee8-880a-c54b11eb7e61' User entered '03 Oct 2020 13:57'	System	03 Oct 2020 18:58:01
	System	03 Oct 2020 18:58:01

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 7'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:00:54', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'dc4b1369-ae56-4189-ad19-7ea1e7871678' User entered 'None (1)'	System	04 Oct 2020 17:04:59
	System	04 Oct 2020 17:04:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:00:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'dc4b1369-ae56-4189-ad19-7ea1e7871678' User entered 'No (N)'	System	04 Oct 2020 17:04:59
	System	04 Oct 2020 17:04:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:01:03', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'dc4b1369-ae56-4189-ad19-7ea1e7871678'	System	04 Oct 2020 17:04:59
User entered 'No (N)'	System	04 Oct 2020 17:04:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:04:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'dc4b1369-ae56-4189-ad19-7ea1e7871678' User entered 'None (1)'	System	04 Oct 2020 17:04:59
	System	04 Oct 2020 17:04:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:04:54', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'dc4b1369-ae56-4189-ad19-7ea1e7871678' User entered '04 Oct 2020 12:04'	System	04 Oct 2020 17:04:59
	System	04 Oct 2020 17:04:59

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:17', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered 'None (0)'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered 'None (0)'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered 'None (0)'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered 'None (0)'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:40', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered 'None (0)'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:42', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered 'None (0)'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:03:48', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered 'No (N)'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-28T12:04:02', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'cfc8b837-3308-4326-9564-529e15d83788' User entered '28 Sep 2020 12:04'	System	28 Sep 2020 17:04:13
	System	28 Sep 2020 17:04:13

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 11:27'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 13:57'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered 'None (0)'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:56:59', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered 'None (0)'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:57:02', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered 'None (0)'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:57:11', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered 'None (0)'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:57:15', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered 'None (0)'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:57:18', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered 'None (0)'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:57:25', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered 'No (N)'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-29T10:57:28', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '22f01d53-9da8-45f1-9a5d-4595cd6485cb' User entered '29 Sep 2020 10:57'	System	29 Sep 2020 15:57:30
	System	29 Sep 2020 15:57:30

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '28 Sep 2020 14:52'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 2'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d' User entered 'None (0)'	System	30 Sep 2020 09:59:17
	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:42', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d' User entered 'None (0)'	System	30 Sep 2020 09:59:17
	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:46', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d' User entered 'None (0)'	System	30 Sep 2020 09:59:17
	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d' User entered 'None (0)'	System	30 Sep 2020 09:59:17
	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:58:59', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d' User entered 'None (0)'	System	30 Sep 2020 09:59:17
	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:59:04', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d' User entered 'None (0)'	System	30 Sep 2020 09:59:17
	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:59:08', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d'	System	30 Sep 2020 09:59:17
User entered 'No (N)'	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-09-30T04:59:15', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '53cfe350-77fe-446f-a51c-4910dc771a2d' User entered '30 Sep 2020 04:59'	System	30 Sep 2020 09:59:17
	System	30 Sep 2020 09:59:17

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 3'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered 'None (0)'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:37', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered 'None (0)'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:41', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered 'None (0)'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:44', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered 'None (0)'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:47', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered 'None (0)'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:50', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered 'None (0)'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:36:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered 'No (N)'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T07:37:01', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5b1f252c-f703-4a18-8a35-6b65592dc4ce' User entered '01 Oct 2020 07:37'	System	01 Oct 2020 12:37:05
	System	01 Oct 2020 12:37:05

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 4'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:00:34', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3'	System	01 Oct 2020 17:01:50
User entered 'None (0)'	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:00:41', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3'	System	01 Oct 2020 17:01:50
User entered 'None (0)'	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:00:46', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3' User entered 'None (0)'	System	01 Oct 2020 17:01:50
	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:00:52', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3' User entered 'None (0)'	System	01 Oct 2020 17:01:50
	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:00:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3' User entered 'None (0)'	System	01 Oct 2020 17:01:50
	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:02', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3'	System	01 Oct 2020 17:01:50
User entered 'None (0)'	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:08', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3'	System	01 Oct 2020 17:01:50
User entered 'No (N)'	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-01T12:01:14', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '459f9774-14c5-4460-8737-27df582736c3'	System	01 Oct 2020 17:01:50
User entered '01 Oct 2020 12:01'	System	01 Oct 2020 17:01:50

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 5'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:16', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered 'None (0)'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:30', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered 'None (0)'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered 'None (0)'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:44', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered 'None (0)'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:46', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered 'None (0)'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:49', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered 'None (0)'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:53', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered 'No (N)'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-02T18:49:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ffe02369-9a48-407a-8989-1990b9dfc1bd' User entered '02 Oct 2020 18:49'	System	02 Oct 2020 23:49:59
	System	02 Oct 2020 23:49:59

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 6'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:07', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered 'None (0)'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered 'None (0)'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:13', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered 'None (0)'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:16', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered 'None (0)'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:18', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered 'None (0)'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:21', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered 'None (0)'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered 'No (N)'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-03T13:58:27', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '26237efc-cab1-4a4a-9e78-1a3c997c424c' User entered '03 Oct 2020 13:58'	System	03 Oct 2020 18:58:33
	System	03 Oct 2020 18:58:33

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	28 Sep 2020 16:16:48
User entered 'Day 7'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:04:58', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435' User entered 'None (0)'	System	04 Oct 2020 17:05:19
	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:05:01', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435' User entered 'None (0)'	System	04 Oct 2020 17:05:19
	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:05:03', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435'	System	04 Oct 2020 17:05:19
User entered 'None (0)'	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:05:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435' User entered 'None (0)'	System	04 Oct 2020 17:05:19
	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:05:08', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435'	System	04 Oct 2020 17:05:19
User entered 'None (0)'	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:05:10', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435' User entered 'None (0)'	System	04 Oct 2020 17:05:19
	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:05:13', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435'	System	04 Oct 2020 17:05:19
User entered 'No (N)'	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-10-04T12:05:16', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5cd276c6-c3e5-47fe-a29f-9b47d67f9435' User entered '04 Oct 2020 12:05'	System	04 Oct 2020 17:05:19
	System	04 Oct 2020 17:05:19

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 16:16:48

US3912046

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 15:10:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 16:16:48

US3912046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 22:34:42

US3912046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '06 Oct 2020'	Amy Collins (b) (4)	06 Oct 2020 22:34:42

US3912046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	06 Oct 2020 22:34:42

US3912046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 22:34:42

US3912046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 22:34:49

US3912046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	06 Oct 2020 22:34:49

US3912046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Mia Rountree (b) (4)	19 Oct 2020 22:14:21

US3912046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '12 Oct 2020'	Mia Rountree (b) (4)	19 Oct 2020 22:14:21

US3912046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Not Made (CONTACT NOT MADE)'	Mia Rountree (b) (4)	19 Oct 2020 22:14:21

US3912046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Called subject five times from the 12th to the 16 and no answer, left messages.'	Mia Rountree (b) (4)	19 Oct 2020 22:14:21

US3912046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Mia Rountree (b) (4)	19 Oct 2020 22:14:28

US3912046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	19 Oct 2020 22:14:28

US3912046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Mia Rountree (b) (4)	19 Oct 2020 22:14:49

US3912046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '19 Oct 2020'	Mia Rountree (b) (4)	19 Oct 2020 22:14:49

US3912046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	19 Oct 2020 22:14:49

US3912046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Mia Rountree (b) (4)	19 Oct 2020 22:14:49

US3912046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Mia Rountree (b) (4)	19 Oct 2020 22:14:54

US3912046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	19 Oct 2020 22:14:54

US3912046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Mia Rountree (b) (4)	02 Nov 2020 16:35:32

US3912046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '2 Nov 2020'	Mia Rountree (b) (4)	02 Nov 2020 16:35:32

US3912046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	02 Nov 2020 16:35:32

US3912046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'VISIT3'	System	02 Nov 2020 16:35:32

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '2 Nov 2020'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '09:00'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered '2 Nov 2020 09:00'	System	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '37.0' C	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '81'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'bpm'	System	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '18'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'breaths/min'	System	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '146'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'mmHg'	System	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '83'	Mia Rountree (b) (4)	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'mmHg'	System	02 Nov 2020 16:36:51

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38

US3912046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38

US3912046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'No (N)'	Mia Rountree (b) (4)	02 Nov 2020 16:36:56

US3912046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered empty.	Mia Rountree (b) (4)	02 Nov 2020 16:36:56

US3912046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 02NOV2020, 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 10:26:34
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 02NOV2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'Lab collected REQ # 1F606646853' (Site from DM).	Mia Rountree (b) (4)	07 Nov 2020 21:56:14
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 02NOV2020, 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 19:10:28
User entered 'Yes (Y)'	Mia Rountree (b) (4)	02 Nov 2020 16:37:08

US3912046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '2 Nov 2020'	Mia Rountree (b) (4)	02 Nov 2020 16:37:08

US3912046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered '09:33'	Mia Rountree (b) (4)	02 Nov 2020 16:37:08

US3912046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered '2 Nov 2020 09:33'	System	02 Nov 2020 16:37:08

US3912046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:06:23
User entered 'Yes (Y)'	Mia Rountree (b) (4)	02 Nov 2020 16:37:12

US3912046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:38
User entered 'I'	System	02 Nov 2020 16:37:12

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 64'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-11-04T12:36:47', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ae231e84-5008-44a9-8017-9d8f98776ace' User entered 'Yes (Y)'	System	04 Nov 2020 22:03:07
	System	04 Nov 2020 22:03:07

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Have you been exposed to someone with 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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-11-04T12:36:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ae231e84-5008-44a9-8017-9d8f98776ace' User entered 'No (N)'	System	04 Nov 2020 22:03:07
	System	04 Nov 2020 22:03:07

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-11-04T12:36:55', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ae231e84-5008-44a9-8017-9d8f98776ace' User entered 'No (N)'	System	04 Nov 2020 22:03:07
	System	04 Nov 2020 22:03:07

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-11-04T12:37:16', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ae231e84-5008-44a9-8017-9d8f98776ace'	System	04 Nov 2020 22:03:07
User entered 'No (N)'	System	04 Nov 2020 22:03:07

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0311FEE3-E867-4C4D-AACE-3D5D249F78CF)', Time: '2020-11-04T12:37:22', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ae231e84-5008-44a9-8017-9d8f98776ace' User entered '04 Nov 2020 12:37:22'	System	04 Nov 2020 22:03:07
	System	04 Nov 2020 22:03:07

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 71'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-07T09:12:21', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '277e3367-79ba-4bae-a36c-540a00925671' User entered 'No (N)'	System	07 Nov 2020 15:12:33
	System	07 Nov 2020 15:12:33

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-07T09:12:25', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '277e3367-79ba-4bae-a36c-540a00925671'	System	07 Nov 2020 15:12:33
User entered 'No (N)'	System	07 Nov 2020 15:12:33

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-07T09:12:31', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '277e3367-79ba-4bae-a36c-540a00925671' User entered '07 Nov 2020 09:12:31'	System	07 Nov 2020 15:12:33
	System	07 Nov 2020 15:12:33

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered 'Day 78'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-14T07:40:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '36dc3995-0f23-4854-b5d8-88706dcd1135'	System	14 Nov 2020 13:40:18
User entered 'No (N)'	System	14 Nov 2020 13:40:18

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-14T07:40:03', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '36dc3995-0f23-4854-b5d8-88706dcd1135'	System	14 Nov 2020 13:40:18
User entered 'No (N)'	System	14 Nov 2020 13:40:18

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-14T07:40:15', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '36dc3995-0f23-4854-b5d8-88706dcd1135'	System	14 Nov 2020 13:40:18
User entered '14 Nov 2020 07:40:15'	System	14 Nov 2020 13:40:18

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 18:36:08

US3912046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:42:51
Data entry locked.	System	31 Aug 2020 18:36:08
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 18:36:08

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-19T15:06:28', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9854fb75-3ee2-4e67-9f19-a1ba970538ac'	System	19 Nov 2020 21:06:43
User entered 'No (N)'	System	19 Nov 2020 21:06:43

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-19T15:06:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9854fb75-3ee2-4e67-9f19-a1ba970538ac' User entered 'No (N)'	System	19 Nov 2020 21:06:43

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-19T15:06:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9854fb75-3ee2-4e67-9f19-a1ba970538ac' User entered '19 Nov 2020 15:06:38'	System	19 Nov 2020 21:06:43
	System	19 Nov 2020 21:06:43

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-26T19:07:47', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd413bde7-d62d-4a54-ba1d-4241faa035b1'	System	27 Nov 2020 01:08:05
User entered 'No (N)'	System	27 Nov 2020 01:08:05

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-26T19:07:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd413bde7-d62d-4a54-ba1d-4241faa035b1'	System	27 Nov 2020 01:08:05
User entered 'No (N)'	System	27 Nov 2020 01:08:05

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-11-26T19:08:01', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd413bde7-d62d-4a54-ba1d-4241faa035b1' User entered '26 Nov 2020 19:08:01'	System	27 Nov 2020 01:08:05
	System	27 Nov 2020 01:08:05

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-02T09:08:17', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5fff7f23-b979-44ee-b30c-78c3e649a8c6'	System	02 Dec 2020 15:08:38
User entered 'No (N)'	System	02 Dec 2020 15:08:38

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-02T09:08:32', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5fff7f23-b979-44ee-b30c-78c3e649a8c6'	System	02 Dec 2020 15:08:38
User entered 'No (N)'	System	02 Dec 2020 15:08:38

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-02T09:08:36', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '5fff7f23-b979-44ee-b30c-78c3e649a8c6' User entered '02 Dec 2020 09:08:36'	System	02 Dec 2020 15:08:38
	System	02 Dec 2020 15:08:38

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-09T08:45:14', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3b17876e-86fa-41cb-aeb8-c82d0be8b15d' User entered 'No (N)'	System	10 Dec 2020 18:03:29
	System	10 Dec 2020 18:03:29

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-09T08:45:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3b17876e-86fa-41cb-aeb8-c82d0be8b15d'	System	10 Dec 2020 18:03:29
User entered 'No (N)'	System	10 Dec 2020 18:03:29

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-09T08:45:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3b17876e-86fa-41cb-aeb8-c82d0be8b15d' User entered '09 Dec 2020 08:45:29'	System	10 Dec 2020 18:03:29
	System	10 Dec 2020 18:03:29

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-16T23:28:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '10f25885-aa03-4237-8251-fc99fd172730'	System	17 Dec 2020 05:28:38
User entered 'No (N)'	System	17 Dec 2020 05:28:38

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-16T23:28:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '10f25885-aa03-4237-8251-fc99fd172730'	System	17 Dec 2020 05:28:38
User entered 'No (N)'	System	17 Dec 2020 05:28:38

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-16T23:28:34', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '10f25885-aa03-4237-8251-fc99fd172730' User entered '16 Dec 2020 23:28:34'	System	17 Dec 2020 05:28:38
	System	17 Dec 2020 05:28:38

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:21:58', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered 'Yes (Y)'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:22:24', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered 'No (N)'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:22:43', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered 'Yes (Y)'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '1'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa' User entered '0'	System	24 Dec 2020 02:25:10
	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa' User entered '0'	System	24 Dec 2020 02:25:10
	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '1'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '1'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '1'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '1'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '1'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa' User entered '0'	System	24 Dec 2020 02:25:10
	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:51', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa'	System	24 Dec 2020 02:25:10
User entered '0'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Please 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:23:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feeaa'	System	24 Dec 2020 02:25:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:09', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feeaa' User entered 'No (N)'	System	24 Dec 2020 02:25:10
	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-23T20:24:57', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'd4381a10-2e4a-482f-924d-0d63fe9feaa' User entered '23 Dec 2020 20:24:57'	System	24 Dec 2020 02:25:10
	System	24 Dec 2020 02:25:10

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-30T07:14:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'aa23d2c2-18ee-46d0-8d30-387b357d5289'	System	30 Dec 2020 13:14:17
User entered 'No (N)'	System	30 Dec 2020 13:14:17

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-30T07:14:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'aa23d2c2-18ee-46d0-8d30-387b357d5289'	System	30 Dec 2020 13:14:17
User entered 'No (N)'	System	30 Dec 2020 13:14:17

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2020-12-30T07:14:15', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'aa23d2c2-18ee-46d0-8d30-387b357d5289' User entered '30 Dec 2020 07:14:15'	System	30 Dec 2020 13:14:17
	System	30 Dec 2020 13:14:17

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-06T09:28:16', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '862fe7b7-e1ae-400c-a7f6-5f7d86ff41e4'	System	06 Jan 2021 15:28:35
User entered 'No (N)'	System	06 Jan 2021 15:28:35

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-06T09:28:20', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '862fe7b7-e1ae-400c-a7f6-5f7d86ff41e4'	System	06 Jan 2021 15:28:35
User entered 'No (N)'	System	06 Jan 2021 15:28:35

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-06T09:28:29', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '862fe7b7-e1ae-400c-a7f6-5f7d86ff41e4' User entered '06 Jan 2021 09:28:29'	System	06 Jan 2021 15:28:35
	System	06 Jan 2021 15:28:35

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-13T13:29:49', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3f70f956-e453-4796-85e2-ed6516d6323d' User entered 'No (N)'	System	13 Jan 2021 19:30:20
	System	13 Jan 2021 19:30:20

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-13T13:29:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3f70f956-e453-4796-85e2-ed6516d6323d' User entered 'No (N)'	System	13 Jan 2021 19:30:20
	System	13 Jan 2021 19:30:20

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-13T13:30:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '3f70f956-e453-4796-85e2-ed6516d6323d' User entered '13 Jan 2021 13:30:00'	System	13 Jan 2021 19:30:20
	System	13 Jan 2021 19:30:20

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-20T07:17:56', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2b2e0fa-ba6e-404f-bbce-b8e9ff8ddaed'	System	20 Jan 2021 13:18:09
User entered 'No (N)'	System	20 Jan 2021 13:18:09

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-20T07:17:18', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2b2e0fa-ba6e-404f-bbce-b8e9ff8ddaed'	System	20 Jan 2021 13:18:09
User entered 'No (N)'	System	20 Jan 2021 13:18:09

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-20T07:18:06', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'b2b2e0fa-ba6e-404f-bbce-b8e9ff8ddaed' User entered '20 Jan 2021 07:18:06'	System	20 Jan 2021 13:18:09
	System	20 Jan 2021 13:18:09

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-27T11:48:31', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a4e9d00f-6baa-41f4-b294-3fc233c9869d' User entered 'No (N)'	System	27 Jan 2021 17:48:45

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-27T11:48:33', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a4e9d00f-6baa-41f4-b294-3fc233c9869d'	System	27 Jan 2021 17:48:45
User entered 'No (N)'	System	27 Jan 2021 17:48:45

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-01-27T11:48:42', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a4e9d00f-6baa-41f4-b294-3fc233c9869d' User entered '27 Jan 2021 11:48:42'	System	27 Jan 2021 17:48:45
	System	27 Jan 2021 17:48:45

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-03T00:03:27', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'eb6ba40d-5d2b-4887-9727-881a6baa437e' User entered 'No (N)'	System	03 Feb 2021 06:03:39
	System	03 Feb 2021 06:03:39

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-03T00:03:31', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'eb6ba40d-5d2b-4887-9727-881a6baa437e' User entered 'No (N)'	System	03 Feb 2021 06:03:39
	System	03 Feb 2021 06:03:39

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-03T00:03:38', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'eb6ba40d-5d2b-4887-9727-881a6baa437e' User entered '03 Feb 2021 00:03:38'	System	03 Feb 2021 06:03:39
	System	03 Feb 2021 06:03:39

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-25T07:54:03-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'aaa43cc4-aeac-4404-9356-eba81f5e222e' User entered 'No (N)'	System	25 Feb 2021 13:54:27

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-25T07:54:08-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'aaa43cc4-aeac-4404-9356-eba81f5e222e' User entered 'Yes (Y)'	System	25 Feb 2021 13:54:27

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Please 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-25T07:54:13-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'aaa43cc4-aeac-4404-9356-eba81f5e222e'	System	25 Feb 2021 13:54:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 13:54:27

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-25T07:54:17-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'aaa43cc4-aeac-4404-9356-eba81f5e222e' User entered '25 Feb 2021 13:54:17'	System	25 Feb 2021 13:54:27
	System	25 Feb 2021 13:54:27

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-03T18:38:30-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a3215f6e-9810-42ac-ba63-8b0e8a04c1cb'	System	04 Mar 2021 00:38:40
User entered 'No (N)'	System	04 Mar 2021 00:38:40

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-03T18:38:34-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a3215f6e-9810-42ac-ba63-8b0e8a04c1cb'	System	04 Mar 2021 00:38:40
User entered 'No (N)'	System	04 Mar 2021 00:38:40

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-03T18:38:38-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a3215f6e-9810-42ac-ba63-8b0e8a04c1cb' User entered '03 Mar 2021 18:38:38'	System	04 Mar 2021 00:38:40
	System	04 Mar 2021 00:38:40

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-10T10:24:20-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ed64020a-8455-4f28-abfa-20880a3cda5b'	System	10 Mar 2021 16:24:31
User entered 'No (N)'	System	10 Mar 2021 16:24:31

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-10T10:24:22-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ed64020a-8455-4f28-abfa-20880a3cda5b'	System	10 Mar 2021 16:24:31
User entered 'No (N)'	System	10 Mar 2021 16:24:31

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-10T10:24:26-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'ed64020a-8455-4f28-abfa-20880a3cda5b' User entered '10 Mar 2021 10:24:26'	System	10 Mar 2021 16:24:31
	System	10 Mar 2021 16:24:31

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-17T00:35:48-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7e1e513a-f86d-467c-a088-8a5f77bf2d01'	System	17 Mar 2021 05:36:02
User entered 'No (N)'	System	17 Mar 2021 05:36:02

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-17T00:35:53-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7e1e513a-f86d-467c-a088-8a5f77bf2d01'	System	17 Mar 2021 05:36:02
User entered 'No (N)'	System	17 Mar 2021 05:36:02

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-17T00:35:58-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '7e1e513a-f86d-467c-a088-8a5f77bf2d01' User entered '17 Mar 2021 00:35:58'	System	17 Mar 2021 05:36:02
	System	17 Mar 2021 05:36:02

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-25T09:57:07-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '99624e22-5ebe-4dc6-8c61-d57f2202b2bd' User entered 'Yes (Y)'	System	25 Mar 2021 14:57:47
	System	25 Mar 2021 14:57:47

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-25T09:57:12-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '99624e22-5ebe-4dc6-8c61-d57f2202b2bd'	System	25 Mar 2021 14:57:47
User entered 'No (N)'	System	25 Mar 2021 14:57:47

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-25T09:57:15-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '99624e22-5ebe-4dc6-8c61-d57f2202b2bd'	System	25 Mar 2021 14:57:47
User entered 'No (N)'	System	25 Mar 2021 14:57:47

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-25T09:57:19-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '99624e22-5ebe-4dc6-8c61-d57f2202b2bd' User entered 'Yes (Y)'	System	25 Mar 2021 14:57:47
	System	25 Mar 2021 14:57:47

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Please 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-25T09:57:26-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '99624e22-5ebe-4dc6-8c61-d57f2202b2bd'	System	25 Mar 2021 14:57:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Mar 2021 14:57:47

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-25T09:57:33-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '99624e22-5ebe-4dc6-8c61-d57f2202b2bd' User entered '25 Mar 2021 09:57:33'	System	25 Mar 2021 14:57:47
	System	25 Mar 2021 14:57:47

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-31T17:08:08-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '19502a5b-45ab-448c-8dda-58a02dea72b1' User entered 'Yes (Y)'	System	31 Mar 2021 22:15:13
	System	31 Mar 2021 22:15:13

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-31T17:08:12-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '19502a5b-45ab-448c-8dda-58a02dea72b1'	System	31 Mar 2021 22:15:13
User entered 'No (N)'	System	31 Mar 2021 22:15:13

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-31T17:08:16-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '19502a5b-45ab-448c-8dda-58a02dea72b1' User entered 'No (N)'	System	31 Mar 2021 22:15:13
	System	31 Mar 2021 22:15:13

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-31T17:08:20-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '19502a5b-45ab-448c-8dda-58a02dea72b1' User entered 'Yes (Y)'	System	31 Mar 2021 22:15:13
	System	31 Mar 2021 22:15:13

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Please 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-31T17:08:24-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '19502a5b-45ab-448c-8dda-58a02dea72b1'	System	31 Mar 2021 22:15:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Mar 2021 22:15:13

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-03-31T17:08:27-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '19502a5b-45ab-448c-8dda-58a02dea72b1'	System	31 Mar 2021 22:15:13
User entered '31 Mar 2021 17:08:27'	System	31 Mar 2021 22:15:13

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-07T08:06:37-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '6c69ff3e-5198-4f2d-ad48-b41c8a1ef2f8'	System	07 Apr 2021 13:06:52
User entered 'No (N)'	System	07 Apr 2021 13:06:52

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-07T08:06:42-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '6c69ff3e-5198-4f2d-ad48-b41c8a1ef2f8'	System	07 Apr 2021 13:06:52
User entered 'No (N)'	System	07 Apr 2021 13:06:52

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-07T08:06:46-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '6c69ff3e-5198-4f2d-ad48-b41c8a1ef2f8'	System	07 Apr 2021 13:06:52
User entered '07 Apr 2021 08:06:46'	System	07 Apr 2021 13:06:52

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-14T15:45:50-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7ba929e-872f-4fa0-a24e-e18da04e85d4'	System	14 Apr 2021 20:46:16
User entered 'No (N)'	System	14 Apr 2021 20:46:16

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-14T15:46:00-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7ba929e-872f-4fa0-a24e-e18da04e85d4'	System	14 Apr 2021 20:46:16
User entered 'No (N)'	System	14 Apr 2021 20:46:16

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-14T15:46:03-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: 'a7ba929e-872f-4fa0-a24e-e18da04e85d4'	System	14 Apr 2021 20:46:16
User entered '14 Apr 2021 15:46:03'	System	14 Apr 2021 20:46:16

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-21T22:23:57-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '68a094ff-3b50-497a-a017-c3eb7ab97d11'	System	22 Apr 2021 03:24:11
User entered 'No (N)'	System	22 Apr 2021 03:24:11

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-21T22:24:00-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '68a094ff-3b50-497a-a017-c3eb7ab97d11'	System	22 Apr 2021 03:24:11
User entered 'No (N)'	System	22 Apr 2021 03:24:11

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-21T22:24:06-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '68a094ff-3b50-497a-a017-c3eb7ab97d11'	System	22 Apr 2021 03:24:11
User entered '21 Apr 2021 22:24:06'	System	22 Apr 2021 03:24:11

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-28T08:29:34-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9d55728d-6bfb-4c89-9a73-016874a53969'	System	29 Apr 2021 00:38:37
User entered 'No (N)'	System	29 Apr 2021 00:38:37

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

Have you been exposed to someone with 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 (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-28T08:29:37-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9d55728d-6bfb-4c89-9a73-016874a53969'	System	29 Apr 2021 00:38:37
User entered 'No (N)'	System	29 Apr 2021 00:38:37

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-04-28T08:29:41-05:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '9d55728d-6bfb-4c89-9a73-016874a53969'	System	29 Apr 2021 00:38:37
User entered '28 Apr 2021 08:29:41'	System	29 Apr 2021 00:38:37

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:55:00

US3912046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:10:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:55:00
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:55:00

US3912046

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 15:10:15

[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 22:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-28T11:14:11-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '93ad8115-380b-4e02-a2f1-e8275d364aa4'	System	28 Feb 2021 17:16:58
User entered 'No (N)'	System	28 Feb 2021 17:16:58

US3912046

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 15:10:15

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57E8DFF9-4567-4C69-9B7C-AF969181C9DB)', Time: '2021-02-28T11:14:21-06:00', User OID: 'PatientReportedOutcome (US3912046)', ODM File OID: '93ad8115-380b-4e02-a2f1-e8275d364aa4' User entered '28 Feb 2021 17:14:21'	System	28 Feb 2021 17:16:58
	System	28 Feb 2021 17:16:58

US3912046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	25 Nov 2020 20:55:21

US3912046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '25 Nov 2020'	(b) (4) Monique Gawlik (b) (4)	25 Nov 2020 20:55:21

US3912046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	25 Nov 2020 20:55:21

US3912046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4)	25 Nov 2020 20:55:21

US3912046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	25 Nov 2020 20:55:27

US3912046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 06:49:37
User entered 'I'	System	25 Nov 2020 20:55:27

US3912046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 19:47:22

US3912046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '30 Dec 2020'	(b) (4)	30 Dec 2020 19:47:22
	Monique Gawlik (b) (4)	

US3912046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 19:47:22

US3912046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4)	30 Dec 2020 19:47:22
	Monique Gawlik (b) (4)	

US3912046

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 19:47:27

US3912046

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User entered 'I'	System	30 Dec 2020 19:47:27

US3912046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Jan 2021 22:03:20

US3912046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '28 Jan 2021'	Tina Rountree (b) (4)	28 Jan 2021 22:03:20

US3912046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Contact Made (CONTACT MADE)'	Tina Rountree (b) (4)	28 Jan 2021 22:03:20

US3912046

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	28 Jan 2021 22:03:20

US3912046

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	Tina Rountree (b) (4)	28 Jan 2021 22:03:34

US3912046

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User entered 'I'	System	28 Jan 2021 22:03:34

US3912046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	Mia Rountree (b) (4)	01 Mar 2021 17:47:52

US3912046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '26 Feb 2021'	Mia Rountree (b) (4)	01 Mar 2021 17:47:52

US3912046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	01 Mar 2021 17:47:52

US3912046

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Mia Rountree (b) (4)	01 Mar 2021 17:47:52

US3912046

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	Mia Rountree (b) (4)	01 Mar 2021 17:47:58

US3912046

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 15:53:23
User entered 'I'	System	01 Mar 2021 17:47:58

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:10:15

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:35
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:23
User entered '26 Oct 2020'		26 Oct 2020 17:51:43

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:10:15

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:35
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:23
User entered '08:53'		26 Oct 2020 17:51:43

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:10:15

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:35
User entered '26 Oct 2020 08:53'	System	26 Oct 2020 17:51:43

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:10:15

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:35
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:23
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'		26 Oct 2020 17:51:43

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:10:15

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:35
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:23
User entered 'Yes (Y)'		26 Oct 2020 17:51:43

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered '26 Oct 2020'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered '0'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered '98'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User entered '%'	System	26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered '98.6' F		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'Mild (Mild)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'Mild (Mild)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'Mild (Mild)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:10:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:34:16
User entered 'None (None)'		26 Oct 2020 17:52:23

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Day 2 (Day 2)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '27 Oct 2020'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '98'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User entered '%'	System	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '98.2' F	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:10:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Day 3 (Day 3)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '28 Oct 2020'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '98'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User entered '%'	System	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '97.4' F	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:10:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Day 4 (Day 4)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '29 Oct 2020'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '98'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User entered '%'	System	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '97.6' F	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:10:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:41
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (None)'	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:37:19

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered '26 Oct 2020'		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[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 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered 'Yes (Y)'		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[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 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered 'No (N)'		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered '26 Oct 2020'		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered empty.		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[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 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered 'No (N)'		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered empty.		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:47
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:14
User entered empty.		03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:10:15

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:47
User entered '0'	System	03 Nov 2020 20:22:32

US3912046

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Jun 2021 15:10:15

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:39:51
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	Mia Rountree (b) (4)	27 Jan 2021 14:55:31

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:10:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User accepted default value 'Day 3 (Day 3)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:10:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:49
User entered 'Yes (Y)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:49
User entered '28 Oct 2020'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Jun 2021 15:10:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User accepted default value 'Day 5 (Day 5)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Jun 2021 15:10:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered empty.		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Jun 2021 15:10:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User accepted default value 'Day 7 (Day 7)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Jun 2021 15:10:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered empty.		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Jun 2021 15:10:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User accepted default value 'Day 9 (Day 9)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Jun 2021 15:10:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered empty.		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Jun 2021 15:10:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User accepted default value 'Day 14 (Day 14)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Jun 2021 15:10:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered empty.		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Jun 2021 15:10:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User accepted default value 'Day 21 (Day 21)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Jun 2021 15:10:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered empty.		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Jun 2021 15:10:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User accepted default value 'Day 28 (Day 28)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Jun 2021 15:10:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered 'NA (COVID-19 Negative) (NA)'		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:54
User entered empty.		03 Nov 2020 20:21:26

US3912046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:21
User entered 'Yes (Y)'		26 Oct 2020 17:53:14

US3912046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:21
User entered '26 Oct 2020'		26 Oct 2020 17:53:14

US3912046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[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 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:21
User entered 'Clinic (Clinic)'		26 Oct 2020 17:53:14

US3912046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User entered 'SICKD1'	System	26 Oct 2020 17:53:14

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered 'Yes (Y)'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '26 Oct 2020'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '09:06'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User entered '26 Oct 2020 09:06'	System	26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '70.0' in		26 Oct 2020 17:54:05
DataPoint set to visible.	System	26 Oct 2020 17:53:14

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '234.0' lb		26 Oct 2020 17:54:05
DataPoint set to visible.	System	26 Oct 2020 17:53:14

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '98.6' F		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered 'Oral (Oral)'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered empty.		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '79'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User entered 'bpm'	System	26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User closed query 'Per CDM: Per CCG V2.0 page 50, RESPIRATORY RATE: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:51:47
Query 'Per CDM: Per CCG V2.0 page 50, RESPIRATORY RATE: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4)	07 Nov 2020 22:06:47
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:35:47
User opened query 'Per CDM: Per CCG V2.0 page 50, RESPIRATORY RATE: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).		02 Nov 2020 16:51:59
User entered '18'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User entered 'breaths/min'	System	26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '169'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User entered 'mmHg'	System	26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:35:47
User entered '95'		26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User entered 'mmHg'	System	26 Oct 2020 17:54:05

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01

US3912046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:10:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01

US3912046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:07
User entered 'Yes (Y)'		26 Oct 2020 17:54:54

US3912046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:07
User entered '26 Oct 2020'		26 Oct 2020 17:54:54

US3912046

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Jun 2021 15:10:15

[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 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:12
User entered 'Yes (Y)'		26 Oct 2020 17:55:02

US3912046

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Jun 2021 15:10:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:01
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:36:12
User entered '26 Oct 2020'		26 Oct 2020 17:55:02

US3912046

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

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 17:53:09
	(b) (4)	

US3912046

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

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 17:53:09
	(b) (4)	

US3912046

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

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	14 Jan 2021 17:53:09
	(b) (4)	

US3912046

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

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 17:53:09

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 17:57:24
	(b) (4)	

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[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 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	09 Mar 2021 18:49:38
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:03:32

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 17:57:24
	(b) (4)	

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sandra Clancy (b) (4)	09 Mar 2021 18:49:38
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:03:32

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 17:57:24
	(b) (4)	

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4)	14 Jan 2021 17:57:24
	(b) (4)	

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:28:23
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4)	14 Jan 2021 17:57:24
	(b) (4)	

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:28:23
User entered 'Placebo (Placebo)'	Tina Rountree (b) (4)	14 Jan 2021 17:57:24
	(b) (4)	

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 17:57:24
	(b) (4)	

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'I'	System	14 Jan 2021 17:57:24

US3912046

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

Form: Unblinding

Generated On: 11 Jun 2021 15:10:15

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'I'	System	14 Jan 2021 17:57:24

US3912046

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
User closed query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:19:24
Query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Mar 2021 22:08:50
User opened query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:15:22
User closed query 'Please add data from 26Feb2021 OL-D1 visit. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:10:02
Query 'Please add data from 26Feb2021 OL-D1 visit. ' answered with 'Data entered' (Site from CRA).	Mia Rountree (b) (4)	17 Mar 2021 16:54:27
Signature has been broken.	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
User opened query 'Please add data from 26Feb2021 OL-D1 visit. ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 20:38:58
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
	(b) (4)	
User entered missing code ND - Not Done; reason for	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
change Data Entry Error	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	01 Feb 2021 17:54:58
DataPoint set to visible.	System	14 Jan 2021 17:57:24

US3912046

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
User closed query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:19:24
Query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Mar 2021 22:08:50
User opened query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:15:22
User closed query 'Please add data from 26Feb2021 OL-D1 visit. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:10:02
Query 'Please add data from 26Feb2021 OL-D1 visit. ' answered with 'Data entered' (Site from CRA).	Mia Rountree (b) (4)	17 Mar 2021 16:54:27
Signature has been broken.	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
User opened query 'Please add data from 26Feb2021 OL-D1 visit. ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 20:38:58
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
	(b) (4)	
User entered missing code ND - Not Done; reason for	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
change Data Entry Error	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	01 Feb 2021 17:54:58
DataPoint set to visible.	System	14 Jan 2021 17:57:24

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User accepted default value 'Pre-Dose (PREDOSE)'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User entered '13:55' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '14:57'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '26 Feb 2021 13:55'	System	17 Mar 2021 22:10:25
User entered '13 Jan 2021 14:57'	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User entered '97.4' F reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '98.0' F	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Oral (Oral)'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User entered '79' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '83'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'bpm'	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User entered '14' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '18'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'breaths/min'	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User entered '154' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '180'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'mmHg'	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User entered '81' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:10:25
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '85'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'mmHg'	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
User closed query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:19:24
Query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4)	17 Mar 2021 22:08:50
User opened query 'Please add Dosing Vital Signs to below Log Lines for 26Feb2021 OL-D1 Visit. Currently, January 13, 2021 vitals are listed. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:15:22
User closed query 'Please add data from 26Feb2021 OL-D1 visit. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:10:02
Query 'Please add data from 26Feb2021 OL-D1 visit. ' answered with 'Data entered' (Site from CRA).	Mia Rountree (b) (4)	17 Mar 2021 16:54:27
Signature has been broken.	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
User opened query 'Please add data from 26Feb2021 OL-D1 visit. ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 20:38:58
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Mia Rountree (b) (4)	17 Mar 2021 16:54:20
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered empty.	System	01 Feb 2021 17:54:58
DataPoint set to visible.	System	14 Jan 2021 17:57:24

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User accepted default value 'Post-Dose (POSTDOSE)'	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 20:08:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 20:08:26
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4)	05 Feb 2021 20:08:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:54:58
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered '16:03' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '26 Feb 2021 16:03'	System	17 Mar 2021 22:12:28
User entered empty.	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered '97.7' F reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered '85' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'bpm'	System	17 Mar 2021 22:12:28
User entered empty.	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered '16' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'breaths/min'	System	17 Mar 2021 22:12:28
User entered empty.	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered '130' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'mmHg'	System	17 Mar 2021 22:12:28
User entered empty.	System	01 Feb 2021 17:54:58

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User entered '71' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:12:28
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:54:58
	(b) (4)	

US3912046

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'mmHg'	System	17 Mar 2021 22:12:28
User entered empty.	System	01 Feb 2021 17:54:58

US3912046

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

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:13:11
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:13:11
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	01 Feb 2021 17:55:15
	(b) (4)	

US3912046

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

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:25:55
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	17 Mar 2021 22:13:11
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	17 Mar 2021 22:13:11
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:55:15
	(b) (4)	

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:10:22
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	01 Feb 2021 17:56:50
	(b) (4)	

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:10:22
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Tina Rountree (b) (4)	01 Feb 2021 17:56:50
	(b) (4)	

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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 11:06:46
User closed query 'Per source, subject completed OL-D1 dosing on 26Feb2021. Please update or clarify. ' (Site from CRA).		12 Mar 2021 20:38:19
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:10:22
Query 'Per source, subject completed OL-D1 dosing on 26Feb2021. Please update or clarify. ' answered with 'Data updated' (Site from CRA).	Mia Rountree (b) (4)	12 Mar 2021 16:25:51
Signature has been broken.	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
User opened query 'Per source, subject completed OL-D1 dosing on 26Feb2021. Please update or clarify. ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 19:10:42
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'subject bp too high. Subject will record bp daily for one week and report back to clinic. If normal, will dose'	Tina Rountree (b) (4)	01 Feb 2021 17:56:50

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'mRNA-1273'	System	12 Mar 2021 16:25:38
User entered empty.	System	01 Feb 2021 17:56:50
DataPoint set to visible.	System	14 Jan 2021 17:57:24

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:10:22
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:56:50
	(b) (4)	

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:10:22
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User entered '15:27' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:56:50
	(b) (4)	

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '26 Feb 2021 15:27'	System	12 Mar 2021 16:25:38
User entered empty.	System	01 Feb 2021 17:56:50

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:10:22
	(b) (4)	
Signature has been broken.	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Mia Rountree (b) (4)	12 Mar 2021 16:25:38
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	01 Feb 2021 17:56:50
	(b) (4)	

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'ONCE'	System	12 Mar 2021 16:25:38
User entered empty.	System	01 Feb 2021 17:56:50

US3912046

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

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 16:25:38
User entered empty.	System	01 Feb 2021 17:56:50

US3912046

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 17:58:07
	(b) (4)	

US3912046

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 17:58:07
	(b) (4)	

US3912046

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '14:29'	Tina Rountree (b) (4)	14 Jan 2021 17:58:07
	(b) (4)	

US3912046

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

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '13 Jan 2021 14:29'	System	14 Jan 2021 17:58:07

US3912046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:10:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 17:58:47
	(b) (4)	

US3912046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '13 Jan 2021'	Tina Rountree (b) (4)	14 Jan 2021 17:58:47
	(b) (4)	

US3912046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered '14:31'	Tina Rountree (b) (4)	14 Jan 2021 17:58:47
	(b) (4)	

US3912046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '13 Jan 2021 14:31'	System	14 Jan 2021 17:58:47

US3912046

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

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	14 Jan 2021 17:58:57
	(b) (4)	

US3912046

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

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:06:46
User entered '1'	System	14 Jan 2021 17:58:57

US3912046

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[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)	12 Mar 2021 19:10:22
User entered 'Yes (Y)'	Mia Rountree (b) (4)	12 Mar 2021 16:27:04

US3912046

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

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)	12 Mar 2021 19:10:22
User entered '8 Mar 2021'	Mia Rountree (b) (4)	12 Mar 2021 16:27:04

US3912046

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[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)	12 Mar 2021 19:10:22
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	12 Mar 2021 16:27:04

US3912046

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[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)	12 Mar 2021 19:10:22
User entered empty.	Mia Rountree (b) (4)	12 Mar 2021 16:27:04

US3912046

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[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
Query 'Please confirm response. Per Adverse Event Source Document, IP withdrawn and second dose not expected. ' canceled (Site from CRA).		30 Mar 2021 16:55:29
User opened query 'Please confirm response. Per Adverse Event Source Document, IP withdrawn and second dose not expected. ' (Site from CRA).		30 Mar 2021 16:55:18
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:10:22
User entered 'Yes (Y)'	(b) (4)	
	Mia Rountree (b) (4)	12 Mar 2021 16:27:10
	(b) (4)	

US3912046

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User entered 'I'	System	12 Mar 2021 16:27:10

US3912046

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User entered 'I'	System	12 Mar 2021 16:27:10
DataPoint set to visible.	System	12 Mar 2021 16:27:10

US3912046

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 14:06:53

US3912046

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 06:46:57
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'confirmed that OL-D29 visit is greater than 42 days from Decision Visit.' (Site from System).	(b) (4) Sandra Clancy (b) (4)	16 Apr 2021 16:44:07
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	15 Apr 2021 14:06:53
User entered '14 Apr 2021'	(b) (4), (b) (6)	15 Apr 2021 14:06:53

US3912046

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Apr 2021 14:06:53

US3912046

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:10:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	15 Apr 2021 14:06:53

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '13:06'	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User entered '14 Apr 2021 13:06'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '98.2' F	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '086'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '016'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '127'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '088'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '15:58'	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User entered '14 Apr 2021 15:58'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '98.0' F	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '086'	(b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '016'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '135'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '075'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:10:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 14:11:12

US3912046

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:45

US3912046

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:10:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:11:45

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	15 Apr 2021 14:12:28
DataPoint set to visible.	System	12 Mar 2021 16:27:10

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered '15:17'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User entered '14 Apr 2021 15:17'	System	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:10:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Apr 2021 14:12:28

US3912046

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	16 Apr 2021 17:08:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:12:50

US3912046

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 14:12:50

US3912046

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 16:50:47
User entered 'Yes (Y)'		22 Apr 2021 18:47:09

US3912046

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 16:50:47
User entered '21 Apr 2021'		22 Apr 2021 18:47:09

US3912046

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 16:50:47
User entered 'Contact Made (CONTACT MADE)'		22 Apr 2021 18:47:09

US3912046

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:10:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 16:50:47
User entered empty.		22 Apr 2021 18:47:09

US3912046

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 16:50:47
User entered 'Yes (Y)'		22 Apr 2021 18:47:17

US3912046

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:10:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 18:47:17

US3912046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Jun 2021 15:10:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:51
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:58:57
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:30:00

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 11:35:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:35:48
Data point term sent to Coder	System	25 Sep 2020 11:32:21
User entered 'hypertension (worsening of)'	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User entered empty.	System	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User entered empty.	System	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:17:36
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:16:49
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #9 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:38:55
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #9 recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Data corrected' (Site from DM).	Mia Rountree (b) (4)	09 Oct 2020 18:22:50
User entered '0' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 18:22:41
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #9 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:20:52
User entered '1'		25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '1' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 18:22:41
User entered '0'	Mia Rountree (b) (4)	25 Sep 2020 11:31:21
	(b) (4)	
	(b) (4), (b) (6)	

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[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 09:00:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:17:45
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.' canceled (Site from Safety).		02 Apr 2021 23:17:42
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		02 Apr 2021 23:16:28
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).		02 Apr 2021 23:13:03
User signature succeeded.		Mark Hutchens (b) (4) 19 Feb 2021 16:05:57
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User entered '0'	System	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26
User entered 'I'	System	25 Sep 2020 11:31:21

US3912046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:10:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Nov 2020 20:19:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:19:25
Data point term sent to Coder	System	03 Nov 2020 20:18:50
User entered 'hypertension (worsening of)'	(b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:19:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 20:19:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:19:00
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:18:26
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User closed query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "HYPERTENSION". Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 12:23:41
Query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "HYPERTENSION". Please clarify and update as appropriate.' answered with 'correct that there are corresponding medications records for HTN; however, for this event of worsening HTN, there was no new treatment/therapy provided. In other words, no new medications that EDC did not have listed.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 18:07:28
User opened query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "HYPERTENSION". Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:30:31
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Nov 2020 20:19:00
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:19:00
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Nov 2020 20:18:26
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:19:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 20:19:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:19:00
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 20:18:26
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:10:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 20:18:26

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 16:35:25
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:52:59
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered	(b) (4)	26 Mar 2021 18:45:04
'USA-US211-2021-mRNA-1273-P301000003'	System	26 Mar 2021 18:45:04
User entered 'New' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Mar 2021 18:45:04
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:44:43

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:03
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Brain stem infarction, LLT: Pontine infarction - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 00:07:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 00:07:42
Data point term sent to Coder	System	05 Apr 2021 18:22:57
DataPoint Un-verified.	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
Coding entries removed.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
User entered 'acute pontine infarct' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Brain stem infarction, LLT: Pontine infarction - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 18:09:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 18:09:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Data point term sent to Coder	(b) (4)	
	System	25 Mar 2021 15:52:46
User entered 'Stroke of the Pons'	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:21
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'No (N)'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:23
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'No (N)'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:27
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '22 Mar 2021'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:31
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	26 Mar 2021 16:12:54
User entered empty; reason for change Data Entry Error	Monique Gawlik (b) (4)	26 Mar 2021 16:12:54
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Mar 2021 16:07:25
User entered '06:00' reason for change: Data Entry Error	Monique Gawlik (b) (4)	26 Mar 2021 16:07:25
User entered empty.	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:12:54
User entered '22 Mar 2021 06:00'	System	26 Mar 2021 16:07:25
User entered empty.	System	25 Mar 2021 15:52:18

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	05 Apr 2021 18:23:41
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 18:23:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Sandra Clancy (b) (4)	05 Apr 2021 18:23:41
DataPoint Verified.	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'Yes (Y)'	(b) (4)	
	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:13
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Apr 2021 18:22:56
DataPoint Un-verified.	Sandra Clancy (b) (4)	05 Apr 2021 18:22:56
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 18:22:56
User entered '30 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 18:22:56
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Apr 2021 18:22:19
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:35
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered empty.	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:37
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered empty.	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:52:18

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:39
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Mar 2021 16:07:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 16:07:25
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	26 Mar 2021 16:07:25
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:52:18
User entered empty.	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:45
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:56
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '0'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'I'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		05 Apr 2021 18:22:19
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		05 Apr 2021 18:22:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Apr 2021 15:27:13
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:53:58
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		29 Mar 2021 10:47:09
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
	(b) (4)	
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Per report subject anticipates discharge home today but has not occurred.' (Site from System).	Monique Gawlik (b) (4)	26 Mar 2021 16:14:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Mar 2021 15:52:18
User entered 'I'	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Form: Adverse Events (3)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:03
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '22 Mar 2021'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:52
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:39:22
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4)	05 Apr 2021 18:23:14
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
User entered '30 Mar 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
DataPoint Verified.	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 23:18:40
		30 Mar 2021 16:54:05
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
	(b) (4)	
User entered empty.	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User closed query 'PER CDM: RE-QUERY: Response noted. However, please record YES/NO for Admitted to ICU? Thank you. ' (Site from DM).	(b) (4)	06 Apr 2021 13:24:46
Query 'PER CDM: RE-QUERY: Response noted. However, please record YES/NO for Admitted to ICU? Thank you. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4)	05 Apr 2021 18:23:20
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Mia Rountree (b) (4)	02 Apr 2021 15:28:03
DataPoint Un-verified.	Mia Rountree (b) (4)	02 Apr 2021 15:27:13
Signature has been broken.	Mia Rountree (b) (4)	02 Apr 2021 15:27:13
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4)	02 Apr 2021 15:27:13
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:07
User opened query 'PER CDM: RE-QUERY: Response noted. However, please record YES/NO for Admitted to ICU? Thank you. ' (Site from DM).		29 Mar 2021 08:40:51
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).		29 Mar 2021 08:40:07
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'was in ICU holding until transferred to a medical unit room.' (Site from System).	Monique Gawlik (b) (4)	26 Mar 2021 16:06:38
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	25 Mar 2021 15:52:18

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNK)'	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:16
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered empty.	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '0'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:21
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '0'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '0'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:44:39
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done' (Site from Safety).	Monique Gawlik (b) (4)	26 Mar 2021 16:13:12
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 16:07:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 16:07:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	26 Mar 2021 16:07:25
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 01:32:57
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:52:18
User entered empty.	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:44:40
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done, please accept' (Site from Safety).	Monique Gawlik (b) (4)	26 Mar 2021 16:13:23
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 16:07:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 16:07:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Monique Gawlik (b) (4)	26 Mar 2021 16:07:25
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 01:33:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:52:18
User entered empty.	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:36
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:38
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '0'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:56:09
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'I'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:55:30
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4)	13 Apr 2021 09:39:50
	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	08 Apr 2021 15:06:07
	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'con med log updated' (Site from DM).	Sandra Clancy (b) (4)	08 Apr 2021 15:05:48
	(b) (4)	
DataPoint Un-verified.	Sandra Clancy (b) (4)	08 Apr 2021 14:42:18
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	08 Apr 2021 14:42:18
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	08 Apr 2021 14:42:18
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:15:29
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:56:12
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
	(b) (4)	
User entered '1'	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18
	(b) (4)	
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:55:33
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		12 Apr 2021 23:59:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'query has been updated.' (Site from Safety).	(b) (4) Sandra Clancy (b) (4)	08 Apr 2021 18:53:51
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 12:43:53
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'the follow up status of the event is unknown as subject is now in rehab.' (Site from Safety).	Sandra Clancy (b) (4)	07 Apr 2021 19:11:33
DataPoint Un-verified.	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
Signature has been broken.	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:23:22
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		02 Apr 2021 23:23:04
DataPoint Verified.		30 Mar 2021 16:56:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)'	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:55:34
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 18:22:19
User entered 'left hemiparesis; dysphagia' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 18:22:19
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:56:16
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
	(b) (4)	
User entered empty.	Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT PRESENTED TO LOCAL ER VIA AMBULANCE ON 22MAR2021 WITH COMPLAINTS OF WEAKNESS OF UPPER AND LOWER LEFT EXTREMITIES AND ALTERED SPEECH. ACCORDING THE THE SUBJECT, HE WAS FINE THE NIGHT BEFORE BUT WHEN HE WOKE UP, HE FELT TINGLINGUPPER/LOWER EXTREMITIES ALONG WITH WEAKNESS AND HAD DIFFICULTY SPEAKING. ON ARRIVAL TO THE ER, MR STROKE PROTOCOL WAS IMPLEMENTED. DUE TO THE TIMELINES, THE SUBJECT WAS OUTSIDE OF THE INTERVENTION WINDOW; HE WAS ADMITTED TO NEUROLOGY FOR FURTHER MANAGEMENT. LAB SAMPLES WERE COLLECTED; IMAGING INCLUDED MRA HEAD AND NECK; CHEST X-RAY; FLUOROSCOPIC BARIUM SWALLOW; TRANSTHORACIC ECHOCARDIOGRAM. RESULTS OF MRI HEAD: VASCULATURE: STENOSIS AT THE LEFT POSTERIOR CEREBRAL ARTERY ORIGIN. MRI OF NECK: MILD PLAQUE OF THE PROXIMAL RIGHT AND LEFT INTERNAL CAROTID ARTERIES MRI OF THE BRAIN: THERE IS DIFFUSION RESTRICTION WITHIN THE PONS BILATERALLY BUT MORE PROMINENT THE RIGHT OF MIDLINE. THERE IS NO ABNORMAL FOCUS OF SUSCEPTIBILITY. MINIMAL PERIVENTRICULAR AND SUBCORTICAL WHITE MATTER T2 HYPERINTENSE SIGNAL NOTED WITHOUT MASS EFFECT. FLUOROSCOPIC BARIUM SWALLOW: FINDINGS WERE MULTIPLE EPISODES OF DEEP PENETRATION. THERE IS FLASH PENETRATION ON ALMOST ALL SWALLOWS WITH ALL CONSISTENCIES EXCEPT FOR THE SOLID BOLUS. CHEST X-RAY: FINDINGS REVEALED HEART IS NORMAL IN SIZE; NO INFILTRATE, PNEUMOTHORAX OR	System	11 Jun 2021 14:45:08

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
EFFUSION; THE MEDIASTINUM AND OSSEOUS STRUCTURES ARE NORMAL. TRANSTHORACIC ECHOCARDIOGRAM: FINDINGS ARE LEFT VENTRICLE CAVITY SIZE IS NORMAL, EF 60-65%. DOPPLER PARAMETERS ARE CONSISTENT WITH ABNORMAL LEFT VENTRICULAR RELAXATION AND NORMAL FILLING PRESSURE (GRADE 1 DIASTOLIC DYSFUNCTION). LEFT ATRIUM: NORMAL IN SIZE ATRIAL SEPTUM: THERE IS NO RIGHT-TO-LEFT ATRIAL LEVEL SHUNT SEEN WITH AGITATED SALINE CONTRAST STUDY. PULMONARY ARTERIES: UNABLE TO ACCURATELY ASSESS SYSTOLIC PRESSURE DUE TO INSUFFICIENT TRICUSPID REGURGITATION JET. NO HEMODYNAMICALLY SIGNIFICANT VALVULAR REGURGITATION OR STENOSIS IDENTIFIED.' (WR#5445128)		
User closed query 'PV Query: Thank you for your response. Query will be closed once result has been received. Please provide dates of laboratory testing listed in case narrative. 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.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:28:05
Query 'PV Query: Thank you for your response. Query will be closed once result has been received. Please provide dates of laboratory testing listed in case narrative. 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.' answered with 'lab results faxed 23Apr2021' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	26 Apr 2021 15:06:39
User opened query 'PV Query: Thank you for your response. Query will be closed once result has been received. Please provide dates of laboratory testing listed in case narrative. 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.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 20:09:43
PRODUCTION RELEASE (v12.003 EAB) (1725)		2073 of 2723

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide dates of laboratory testing listed in case narrative. 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.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 16:41:16
Query 'PV Query: Please provide dates of laboratory testing listed in case narrative. 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.' answered with 'lab results to be faxed to Safety today' (Site from Safety).	Sandra Clancy (b) (4)	21 Apr 2021 20:45:02
User opened query 'PV Query: Please provide dates of laboratory testing listed in case narrative. 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.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 20:00:10
User closed query 'PV Query: Thank you for your response. Please provide dates of laboratory testing listed in case narrative in query response. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 17:46:53
Query 'PV Query: Thank you for your response. Please provide dates of laboratory testing listed in case narrative in query response. ' answered with 'There is no available 'space' for additional data to be placed in the narrative' (Site from Safety).	Sandra Clancy (b) (4)	20 Apr 2021 13:36:26
User opened query 'PV Query: Thank you for your response. Please provide dates of laboratory testing listed in case narrative in query response. ' (Site from Safety).	(b) (4), (b) (6)	0 Apr 2021 12:47:28
DataPoint Verified.	(b) (4), (b) (6)	6 Apr 2021 21:55:52
User signature succeeded.	(b) (4), (b) (6)	3 Apr 2021 16:34:33
User closed query 'PV Query: Please provide dates of laboratory testing listed in case narrative if available.' (Site from Safety).	(b) (4), (b) (6)	3 Apr 2021 16:11:31
User closed query 'PV Query: Obesity is mentioned as a predisposing factor for the event. Please consider adding obesity so subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	3 Apr 2021 16:11:29

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide dates of laboratory testing listed in case narrative if available.' answered with 'narrative field will not allow any additional characters.' (Site from Safety). Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:59:53
	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:59:10

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT PRESENTED TO LOCAL ER VIA AMBULANCE ON 22MAR2021 WITH COMPLAINTS OF WEAKNESS OF UPPER AND LOWER LEFT EXTREMITIES AND ALTERED SPEECH. ACCORDING THE THE SUBJECT, HE WAS FINE THE NIGHT BEFORE BUT WHEN HE WOKE UP, HE FELT TINGLINGUPPER/LOWER EXTREMITIES ALONG WITH WEAKNESS AND HAD DIFFICULTY SPEAKING. ON ARRIVAL TO THE ER, MR STROKE PROTOCOL WAS IMPLEMENTED. DUE TO THE TIMELINES, THE SUBJECT WAS OUTSIDE OF THE INTERVENTION WINDOW; HE WAS ADMITTED TO NEUROLOGY FOR FURTHER MANAGEMENT. LAB SAMPLES WERE COLLECTED; IMAGING INCLUDED MRA HEAD AND NECK; CHEST X-RAY; FLUOROSCOPIC BARIUM SWALLOW; TRANSTHORACIC ECHOCARDIOGRAM. RESULTS OF MRI HEAD: VASCULATURE: STENOSIS AT THE LEFT POSTERIOR CEREBRAL ARTERY ORIGIN. MRI OF NECK: MILD PLAQUE OF THE PROXIMAL RIGHT AND LEFT INTERNAL CAROTID ARTERIES MRI OF THE BRAIN: THERE IS DIFFUSION RESTRICTION WITHIN THE PONS BILATERALLY BUT MORE PROMINENT THE RIGHT OF MIDLINE. THERE IS NO ABNORMAL FOCUS OF SUSCEPTIBILITY. MINIMAL PERIVENTRICULAR AND SUBCORTICAL WHITE MATTER T2 HYPERINTENSE SIGNAL NOTED WITHOUT MASS EFFECT. FLUOROSCOPIC BARIUM SWALLOW: FINDINGS WERE MULTIPLE EPISODES OF DEEP PENETRATION. THERE IS FLASH PENETRATION ON ALMOST ALL SWALLOWS WITH ALL CONSISTENCIES EXCEPT FOR THE SOLID BOLUS. CHEST X-RAY: FINDINGS REVEALED HEART IS NORMAL	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:59:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
IN SIZE; NO INFILTRATE, PNEUMOTHORAX OR EFFUSION; THE MEDIASTINUM AND OSSEOUS STRUCTURES ARE NORMAL. TRANSTHORACIC ECHOCARDIOGRAM: FINDINGS ARE LEFT VENTRICLE CAVITY SIZE IS NORMAL, EF 60-65%. DOPPLER PARAMETERS ARE CONSISTENT WITH ABNORMAL LEFT VENTRICULAR RELAXATION AND NORMAL FILLING PRESSURE (GRADE 1 DIASTOLIC DYSFUNCTION). LEFT ATRIUM: NORMAL IN SIZE ATRIAL SEPTUM: THERE IS NO RIGHT-TO-LEFT ATRIAL LEVEL SHUNT SEEN WITH AGITATED SALINE CONTRAST STUDY. PULMONARY ARTERIES: UNABLE TO ACCURATELY ASSESS SYSTOLIC PRESSURE DUE TO INSUFFICIENT TRICUSPID REGURGITATION JET. NO HEMODYNAMICALLY SIGNIFICANT VALVULAR REGURGITATION OR STENOSIS IDENTIFIED.'		
reason for change: Data Entry Error Query 'PV Query: Obesity is mentioned as a predisposing factor for the event. Please consider adding obesity so subject's medical history.' answered with 'medical history updated per query request' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 13:45:55
User opened query 'PV Query: Please provide dates of laboratory testing listed in case narrative if available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:04:53
User opened query 'PV Query: Obesity is mentioned as a predisposing factor for the event. Please consider adding obesity so subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:04:41
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Apr 2021 14:00:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:49:46

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'see narrative' (Site from Safety).	Sandra Clancy (b) (4)	06 Apr 2021 15:25:35
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4)	
User closed query '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)	06 Apr 2021 13:40:08
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).		06 Apr 2021 13:39:56
		06 Apr 2021 13:39:48

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT PRESENTED TO LOCAL ER VIA AMBULANCE ON 22MAR2021 WITH COMPLAINTS OF WEAKNESS OF UPPER AND LOWER LEFT EXTREMITIES AND ALTERED SPEECH. ACCORDING THE THE SUBJECT, HE WAS FINE THE NIGHT BEFORE BUT WHEN HE WOKE UP, HE FELT TINGLINGUPPER/LOWER EXTREMITIES ALONG WITH WEAKNESS AND HAD DIFFICULTY SPEAKING. ON ARRIVAL TO THE ER, MR STROKE PROTOCOL WAS IMPLEMENTED. DUE TO THE TIMELINES, THE SUBJECT WAS OUTSIDE OF THE INTERVENTION WINDOW; HE WAS ADMITTED TO NEUROLOGY FOR FURTHER MANAGEMENT. LAB SAMPLES WERE COLLECTED; IMAGING INCLUDED MRA HEAD AND NECK; CHEST X-RAY; FLUOROSCOPIC BARIUM SWALLOW; TRANSTHORACIC ECHOCARDIOGRAM. Results of MRI Head: Vasculature: stenosis at the left posterior cerebral artery origin. MRI of Neck: mild plaque of the proximal right and left internal carotid arteries MRI of the Brain: there is diffusion restriction within the pons bilaterally but more prominent the right of midline. There is no abnormal focus of susceptibility. Minimal periventricular and subcortical white matter T2 hyperintense signal noted without mass effect. Fluoroscopic barium swallow: findings were multiple episodes of deep penetration. There is flash penetration on almost all swallows with all consistencies except for the solid bolus. Chest x-ray: findings revealed heart is normal in size; no infiltrate, pneumothorax or effusion; the mediastinum and osseous structures are normal. Transthoracic echocardiogram: findings are left ventricle cavity size is normal, EF 60-65%. Doppler parameters are consistent with abnormal left ventricular relaxation and normal filling pressure (grade 1 diastolic dysfunction). left atrium:	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 20:37:31

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
normal in size atrial septum: there is no right-to-left atrial level shunt seen with agitated saline contrast study. pulmonary arteries: unable to accurately assess systolic pressure due to insufficient tricuspid regurgitation jet. No hemodynamically significant valvular regurgitation or stenosis identified.' reason for change: Data Entry Error		
User entered 'THE SUBJECT PRESENTED TO LOCAL ER VIA AMBULANCE ON 22MAR2021 WITH COMPLAINTS OF WEAKNESS OF UPPER AND LOWER LEFT EXTREMITIES AND ALTERED SPEECH. ACCORDING THE THE SUBJECT, HE WAS FINE THE NIGHT BEFORE BUT when he woke up, HE FELT TINGLINGUPPER/LOWER EXTREMITIES along with weakness AND HAD DIFFICULTY SPEAKING. ON ARRIVAL TO THE ER, MR STROKE PROTOCOL WAS IMPLEMENTED. DUE TO THE TIMELINES, THE SUBJECT WAS OUTSIDE OF THE INTERVENTION WINDOW; HE WAS ADMITTED TO NEUROLOGY FOR FURTHER MANAGEMENT. LAB SAMPLES WERE COLLECTED; IMAGING INCLUDED MRA HEAD AND NECK; CHEST X-RAY; FLUOROSCOPIC BARIUM SWALLOW; TRANSTHORACIC ECHOCARDIOGRAM.'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 20:19:34
reason for change: Data Entry Error		
Query '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 meds updated' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:38:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'The subject presented to local ER via ambulance on 22Mar2021 with complaints of weakness of upper and lower left extremities and altered speech. According the the subject, he was fine the night before but upon waking this day, found that he felt tingling in left upper/lower extremities and had difficulty speaking. Upon arrival to the ER, MR stroke protocol was implemented. Due to the timelines, the subject was outside of the intervention window; he was admitted to neurology for further management. Lab samples were collected; imaging included MRA Head and Neck; chest x-ray; fluoroscopic barium swallow; transthoracic echocardiogram.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:08:48
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'pre-disposing factors: diabetes, hypertension, obesity, hyperlipidemia' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 18:31:27
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 'during the hospitalization on 22Mar2021 nasopharyngeal swab was collected - testing was negative for Covid-19' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 18:27:50
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 18:22:19
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 18:22:19
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 18:22:19
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:21:21
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Apr 2021 23:20:43

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Folder: Adverse Events

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Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query '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)	02 Apr 2021 23:19:35
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).		02 Apr 2021 23:19:09
DataPoint Verified.		30 Mar 2021 16:56:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered 'Site has not collected details yet. Just received message today and PI notified.'	(b) (4) Monique Gawlik (b) (4)	25 Mar 2021 15:52:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:10:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:52:18

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Apr 2021 19:13:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 19:13:34
Data point term sent to Coder	System	05 Apr 2021 19:12:33
User entered 'restless leg syndrome'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:11:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:11:44

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'I'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:11:44
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:11:44

US3912046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:10:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:11:44

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Cerebral artery stenosis, LLT: Posterior cerebral artery stenosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Apr 2021 12:28:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 12:28:46
Data point term sent to Coder	System	05 Apr 2021 19:18:43
User entered 'stenosis, left posterior cerebral artery'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '22 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	05 Apr 2021 19:37:47
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:37:47
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Apr 2021 19:17:46
User entered '15:36'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:37:47
User entered '22 Mar 2021 15:36'	System	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Apr 2021 14:00:37
User entered empty.	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered 'I'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG V5, page no 52, Outcome of AE can be unknown when subject s lost to follow up, however here it is recorded as UNKNOWN and end of study form is absent, kindly update or confirm, Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 07:11:24
Query 'Per CDM: As per CCG V5, page no 52, Outcome of AE can be unknown when subject s lost to follow up, however here it is recorded as UNKNOWN and end of study form is absent, kindly update or confirm, Thank you.' answered with 'as noted in the narrative, this was a finding - there is no other mention of course of treatment. it was picked up as an AE due to change from baseline history. Outcome is unknown.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	12 Apr 2021 14:02:45
User opened query 'Per CDM: As per CCG V5, page no 52, Outcome of AE can be unknown when subject s lost to follow up, however here it is recorded as UNKNOWN and end of study form is absent, kindly update or confirm, Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 10:18:49
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Apr 2021 14:00:37
User entered 'Unknown (UNKNOWN)'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:17:46
	(b) (4)	

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'this event was a finding noted on the magnetic resonance imaging report dated 22Mar2021. No further remarks are found regarding the event.'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:10:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:17:46

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Left ventricular hypertrophy, LLT: Left ventricular hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 18:06:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 18:06:46
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 18:06:15
User entered 'left ventricular hypertrophy'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '22 Mar 2021'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 13:52:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 13:52:41
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Apr 2021 13:52:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 18:05:22
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 13:52:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 13:52:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Apr 2021 13:52:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 18:05:22
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Apr 2021 14:00:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 18:05:22

US3912046

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:10:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 18:05:22

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 15:10:15

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:51
DataPoint Verified.		30 Mar 2021 17:00:24
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:23:22

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 18:25:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:25:36
Data point term sent to Coder	System	06 Sep 2020 18:24:52
User entered 'Losartan'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:24:11

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Hypertension'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '120'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'mg (mg)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once daily (QD)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'un Feb 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:39:53
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:39:53
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:39:53
	(b) (4)	
User entered '30 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:39:53
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:11
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:24:11

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:24:11

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 18:24:11

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: PHENYLALKYLAMINE DERIVATIVES, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 18:26:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:26:36
Data point term sent to Coder User entered 'Verapamil'	System Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:25:53 06 Sep 2020 18:24:56

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Hypertension'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '100'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'mg (mg)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'once daily (QD)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'un UNK 2019'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:24:56
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:24:56

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:24:56

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 18:24:56

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: METFORMIN ER - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Sep 2020 18:27:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:27:36
Data point term sent to Coder	System	06 Sep 2020 18:26:53
User entered 'Metformin ER'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:25:53

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Type II diabetes'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '500'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'mg (mg)'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'once daily (QD)'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'un Feb 2019'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:40:38
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:40:38
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:40:38
	(b) (4)	
User entered '30 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:40:38
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:25:53
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:25:53

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:25:53

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 18:25:53

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
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 HUMAN, PRODUCTSYNONYM: NOVOLIN R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 14:41:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 14:41:44
Data point term sent to Coder	System	04 Oct 2020 19:15:29
Coding entries removed.	Timothy Vachris (b) (4)	04 Oct 2020 19:15:27
User entered 'NOVOLIN R' reason for change: Data Entry Error	Timothy Vachris (b) (4)	04 Oct 2020 19:15:27
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 HUMAN, PRODUCTSYNONYM: NOVOLIN R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:27:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:27:44
Data point term sent to Coder	System	06 Sep 2020 18:27:54
User entered 'Noxolin R'	Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Type II Diabetes'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '30'	(b) (4) Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	
	Timothy Vachris (b) (4)	04 Oct 2020 19:15:27
User entered 'Other (OTHER)'	(b) (4)	
	Tina Rountree (b) (4)	06 Sep 2020 18:27:06
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User closed query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 07:56:12
Query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'corrected' (Site from DM).	Timothy Vachris (b) (4) (b) (4)	04 Oct 2020 19:15:35
User entered empty; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	04 Oct 2020 19:15:27
User opened query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 10:59:39
User entered 'Units'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once daily (QD)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'un UNK 2017'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:41:56
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:41:56
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:41:56
User entered '22 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:41:56
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User entered '1'	System	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User entered '1'	System	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:11
User entered '804 (804)'	System	06 Sep 2020 18:27:06

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
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, INTERMEDIATE-ACTING, PRODUCT: INSULIN HUMAN INJECTION, ISOPHANE, PRODUCTSYNONYM: NOVOLIN N - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 18:29:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:29:36
Data point term sent to Coder	System	06 Sep 2020 18:28:55
User entered 'Novolin N'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Type II Diabetes'	(b) (4) Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '30'	(b) (4) Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	
	Timothy Vachris (b) (4)	04 Oct 2020 19:15:50
User entered 'Other (OTHER)'	(b) (4)	
	Tina Rountree (b) (4)	06 Sep 2020 18:28:01
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User closed query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 07:56:34
Query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'corrected' (Site from DM).	Timothy Vachris (b) (4) (b) (4)	04 Oct 2020 19:15:56
User entered empty; reason for change Data Entry Error	Timothy Vachris (b) (4) (b) (4)	04 Oct 2020 19:15:50
User opened query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:00:11
User entered 'Units'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'as needed (PRN)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'un UNK 2017'	(b) (4) Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	(b) (4) Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:42:20
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:42:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:42:20
User entered '22 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:42:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User entered empty.	System	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User entered empty.	System	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:16
User entered empty.	System	06 Sep 2020 18:28:01

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 18:30:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:30:36
Data point term sent to Coder	System	06 Sep 2020 18:29:55
User entered 'Atorvastatin'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:29:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Hyperlipedemia'	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 18:58:53
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 18:29:08
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:58:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 18:58:53
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:58:53
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 18:29:08
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once daily (QD)'	(b) (4) Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '18 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:43:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:43:05
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
Signature has been broken.	Sandra Clancy (b) (4)	05 Apr 2021 19:43:05
	(b) (4)	
User entered '30 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:43:05
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:29:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 18:29:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 18:29:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 18:30:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:30:36
Data point term sent to Coder User entered 'Aspirin'	System Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:29:55 06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Cardiac prophylaxis'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '81'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'mg (mg)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once daily (QD)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '18 Aug 2020'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:59:42
User entered 'Yes (Y)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:59:42
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User entered '1'	System	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User entered '1'	System	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:32
User entered '804 (804)'	System	06 Sep 2020 18:29:50

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 18:31:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 18:31:36
Data point term sent to Coder	System	06 Sep 2020 18:30:56
User entered 'Loperamide'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Irritable Bowel Syndrome'	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '2'	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'mg (mg)'	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
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	24 Sep 2020 18:59:17
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:59:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 18:30:47
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:30:47
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'un UNK 2015'	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	Tina Rountree (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:55
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
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	24 Sep 2020 18:59:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:59:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 18:30:47
User entered empty.	Tina Rountree (b) (4)	06 Sep 2020 18:30:47
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User entered empty.	System	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User entered empty.	System	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:36
User entered empty.	System	06 Sep 2020 18:30:47

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Nov 2020 06:28:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:28:50
Data point term sent to Coder Coding entries removed.	System Monique Gawlik (b) (4)	18 Nov 2020 21:49:20 18 Nov 2020 21:49:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:02:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 19:02:39
Data point term sent to Coder User entered 'hydrochlorothiazide'	System (b) (4), (b) (6)	24 Sep 2020 19:01:28 24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'HYPERTENSION (Worsening of) AE' reason for change: Data Entry Error	(b) (4) Monique Gawlik (b) (4)	18 Nov 2020 21:49:07
User entered 'hypertension'	(b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '25'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 19:43:39
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:43:39
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
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 Feb 2021 08:38:46
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 'Confirmed that medication is still ongoing' (Site from DM).	Mia Rountree (b) (4)	22 Feb 2021 19:15:20
	(b) (4)	
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)	19 Jan 2021 13:33:22
User entered 'Yes (Y)'		24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 19:43:39
	(b) (4)	
User entered '25 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:43:39
	(b) (4)	
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User entered '1'	System	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User entered '1'	System	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:15:24
User entered '804 (804)'	System	24 Sep 2020 19:01:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 18:47:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:47:39
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4) (b) (4)	09 Mar 2021 18:46:32 09 Mar 2021 18:45:36
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) (b) (4)	26 Oct 2020 19:12:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:12:29
Data point term sent to Coder User entered 'aspirin'	System (b) (4), (b) (6)	26 Oct 2020 18:05:49 26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Cardiac prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4)	11 Mar 2021 07:04:49
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Cardiac prophylaxis). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4)	09 Mar 2021 18:45:46
User entered 'CARDIAC prophylaxis' reason for change: Data Entry Error	Sandra Clancy (b) (4)	09 Mar 2021 18:45:36
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Cardiac prophylaxis). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:19:48
User entered 'cardiac'	(b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '325'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 19:44:13
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:44:13
User signature succeeded.	(b) (4)	
	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 19:44:13
	(b) (4)	
User entered '24 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	05 Apr 2021 19:44:13
User signature succeeded.	(b) (4)	
	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User entered '1'	System	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User entered '1'	System	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:43
User entered '804 (804)'	System	26 Oct 2020 18:05:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening IBS should be recorded, and update con med indication or provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Hutchens (b) (4)	11 Mar 2021 07:05:01 09 Mar 2021 19:52:59
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening IBS should be recorded, and update con med indication or provide clarification. ' answered with 'it is to treat condition noted in med history - not worsening. ' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	09 Mar 2021 18:48:08
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening IBS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 02:51:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: BUTYRIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:10:18
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 Nov 2020 05:10:18
Data point term sent to Coder	System	03 Nov 2020 20:23:59
User entered 'butyric acid'	(b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'IBS'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '1'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.		03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 20:23:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 Nov 2020 20:23:07
DataPoint inactivated with code reason code Data not required.		26 Oct 2020 18:06:18

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:49:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:49:35
Data point term sent to Coder	System	04 Nov 2020 22:48:18
User entered 'Influenza Vaccine'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Yes (Y)'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Flu prevention'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0.5'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'mL (mL)'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'once (ONCE)'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'Intramuscular (INTRAMUSCULAR)'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered empty.	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '02 Nov 2020'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '0'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered 'No (N)'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User entered '02 Nov 2020'	Mia Rountree (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:52:59
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 10:43:55
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'date entry error' (Site from DM).	Tina Rountree (b) (4) (b) (4)	18 Jan 2021 20:04:06
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	18 Jan 2021 20:03:06
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 02:51:24
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User entered empty.	System	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User entered empty.	System	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:19:46
User entered empty.	System	04 Nov 2020 22:47:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 19:47:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:47:25
Data point term sent to Coder	System	05 Apr 2021 19:46:35
User entered 'atorvastatin'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:46:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'hyperlipidemia'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '40'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'mg (mg)'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'once daily (QD)'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '24 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:46:08
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:46:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:46:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:46:08

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 19:48:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:48:24
Data point term sent to Coder	System	05 Apr 2021 19:47:37
User entered 'metformin'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:47:23

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'diabetes mellitus'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '500'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'mg (mg)'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'twice daily (BID)'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '31 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:47:23
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Apr 2021 19:47:23

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:47:23

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:47:23

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:49:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 19:49:31
Data point term sent to Coder	System	05 Apr 2021 19:48:38
User entered 'gabapentin'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'restless leg syndrome'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '300'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'mg (mg)'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'once daily (QD)'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:48:33
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:48:33

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:48:33

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:48:33

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
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) (b) (4)	06 Apr 2021 04:35:48
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 Apr 2021 04:35:48
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 20:51:21
Data point term sent to Coder	System	05 Apr 2021 19:50:39
User entered 'aspirin'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'acute pontine infarct'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '300'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'mg (mg)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4)	
	Sandra Clancy (b) (4)	05 Apr 2021 19:50:20
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'once (ONCE)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'Rectal (RECTAL)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '22 Mar 2021'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '0'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '22 Mar 2021'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
DataPoint Verified.		16 Apr 2021 21:58:55
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
User entered empty.	System	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
User entered empty.	System	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:48
User entered empty.	System	05 Apr 2021 19:50:20

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:30:57
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 Apr 2021 12:30:57
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 20:51:21
Data point term sent to Coder	System	05 Apr 2021 19:51:41
User entered 'lovenox'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'acute pontine infarct'	Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '40'	Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'mg (mg)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'once daily (QD)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '22 Mar 2021'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '0'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '30 Mar 2021'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:58:56
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:51:32

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
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: NOVOLOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 19:54:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:54:23
Data point term sent to Coder	System	05 Apr 2021 19:53:44
User entered 'novolog'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:52:55

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'diabetes mellitus'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'sliding scale'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Other (OTHER)'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'units'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'as needed (PRN)'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:52:55

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '24 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:52:55
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:52:55

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:52:55

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:52:55

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 19:57:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:57:32
Data point term sent to Coder	System	05 Apr 2021 19:56:49
User entered 'hydrochlorothiazide'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:56:25

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'hypertension'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '12.5'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'mg (mg)'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'once daily (QD)'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '25 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:56:25
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:56:25

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:56:25

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:56:25

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 19:58:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:58:33
Data point term sent to Coder	System	05 Apr 2021 19:57:50
User entered 'losartan'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:57:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'hypertension'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '50'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'mg (mg)'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'once daily (QD)'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '25 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 19:57:19
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:57:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:57:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:57:19

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
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) (b) (4)	06 Apr 2021 11:09:52
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 Apr 2021 11:09:52
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 20:51:21
Data point term sent to Coder	System	05 Apr 2021 19:59:56
User entered 'aspirin'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'acute pontine infarct, post care'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '81'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'mg (mg)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'once daily (QD)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'Oral (ORAL)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '24 Mar 2021'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '0'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:00:18
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4)	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:58:58

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 20:01:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:01:24
Data point term sent to Coder	System	05 Apr 2021 20:01:01
User entered 'labetalol'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'hypertension'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '10'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'mg (mg)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'once (ONCE)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'Intravenous (INTRAVENOUS)'	Sandra Clancy (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '25 Mar 2021'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '0'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered '25 Mar 2021'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User entered empty.	System	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User entered empty.	System	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:58
User entered empty.	System	05 Apr 2021 19:59:59

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
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 DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:02:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 20:02:43
Data point term sent to Coder	System	05 Apr 2021 20:02:10
User entered 'losartan potassium/hydrochlorothiazide'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'hypertension'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '12.5/50'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'mg (mg)'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'once daily (QD)'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 20:01:49
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:01:49

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:01:49

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 20:01:49

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:59:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:59:45
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	05 Apr 2021 20:51:21
Data point term sent to Coder	System	05 Apr 2021 20:03:12
User entered 'sitagliptin'	Sandra Clancy (b) (4) (b) (4)	05 Apr 2021 20:02:34

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'diabetes mellitus'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '100'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'mg (mg)'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'once daily (QD)'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered '0'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 20:51:21
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	05 Apr 2021 20:02:34
	(b) (4)	

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:02:34

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:02:34

US3912046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Jun 2021 15:10:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 20:02:34

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Jun 2021 15:10:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:51
DataPoint Verified.	(b) (4)	16 Apr 2021 22:00:51
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	08 Apr 2021 14:51:32
Signature has been broken.	(b) (4)	
	Sandra Clancy (b) (4)	08 Apr 2021 14:51:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	08 Apr 2021 14:51:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 17:01:33
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:05:57
	(b) (4)	
User entered 'No (N)'	Tina Rountree (b) (4)	06 Sep 2020 18:31:00
	(b) (4)	

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:10:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
	(b) (4)	
User entered '23 Mar 2021'	Sandra Clancy (b) (4)	08 Apr 2021 14:52:25
	(b) (4)	

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:10:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
	(b) (4)	
User entered 'transthoracic echocardiogram'	Sandra Clancy (b) (4)	08 Apr 2021 14:52:25
	(b) (4)	

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
	(b) (4)	
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4)	08 Apr 2021 14:52:25
	(b) (4)	

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:10:15

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	08 Apr 2021 14:52:25
	(b) (4)	

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:10:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:24
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered '22 Mar 2021'	Sandra Clancy (b) (4)	08 Apr 2021 14:53:11

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:10:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:24
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'magnetic resonance imaging'	Sandra Clancy (b) (4)	08 Apr 2021 14:53:11

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:24
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4)	08 Apr 2021 14:53:11

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:10:15

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:24
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Apr 2021 14:53:11

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:10:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:28
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered '22 Mar 2021'	Sandra Clancy (b) (4)	08 Apr 2021 14:54:25

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:10:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:28
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'x-ray chest'	Sandra Clancy (b) (4)	08 Apr 2021 14:54:25

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:28
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4)	08 Apr 2021 14:54:25

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:10:15

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:28
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Apr 2021 14:54:25

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:10:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:32
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered '23 Mar 2021'	Sandra Clancy (b) (4)	08 Apr 2021 14:55:01

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:10:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:32
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'fluoroscopic barium swallow'	Sandra Clancy (b) (4)	08 Apr 2021 14:55:01

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:32
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4)	08 Apr 2021 14:55:01

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:10:15

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:32
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Apr 2021 14:55:01

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:10:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:36
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered '22 Mar 2021'	Sandra Clancy (b) (4)	08 Apr 2021 14:57:11

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:10:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:36
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'echocardiogram'	Sandra Clancy (b) (4)	08 Apr 2021 14:57:11

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:10:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:36
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered 'Adverse Event (AE)'	Sandra Clancy (b) (4)	08 Apr 2021 14:57:11

US3912046

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:10:15

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:41:36
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 16:06:01
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Apr 2021 14:57:11

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'USA-US211-2021-MRNA-1273-P301000003'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Mark'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Hutchens'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'US'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 13:23:23
User entered '4'	System	08 Apr 2021 19:54:59
User entered '3'	System	06 Apr 2021 13:41:45
User entered '2'	System	05 Apr 2021 16:36:00
User entered '1'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'USA-US211-2021-MRNA-1273-P301000003'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Mark'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Hutchens'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'US'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 13:23:23
User entered '4'	System	08 Apr 2021 19:54:59
User entered '3'	System	06 Apr 2021 13:41:45
User entered '2'	System	05 Apr 2021 16:36:00
User entered '1'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 15:10:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
User entered '26/Mar/2021 14:45'	(b) (4) System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 15:10:15

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)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'USA-US211-2021-MRNA-1273-P301000003'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Mark'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Hutchens'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'US'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 13:23:23
User entered '4'	System	08 Apr 2021 19:54:59
User entered '3'	System	06 Apr 2021 13:41:45
User entered '2'	System	05 Apr 2021 16:36:00
User entered '1'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 15:10:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 18:13:22
User entered '05/Apr/2021 12:35'	(b) (4) System	05 Apr 2021 16:36:00

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 15:10:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
Reviewed for Safety.		06 Apr 2021 13:41:27
User signature succeeded.	Mark Hutchens (b) (4)	05 Apr 2021 18:13:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:36:00

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'USA-US211-2021-MRNA-1273-P301000003'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Mark'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Hutchens'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'US'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 13:23:23
User entered '4'	System	08 Apr 2021 19:54:59
User entered '3'	System	06 Apr 2021 13:41:45
User entered '2'	System	05 Apr 2021 16:36:00
User entered '1'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 15:10:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 15:47:04
User entered '06/Apr/2021 09:41'	(b) (4) System	06 Apr 2021 13:41:45

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 15:10:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 15:47:04
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 13:41:45

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'USA-US211-2021-MRNA-1273-P301000003'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Mark'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Hutchens'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'US'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 13:23:23
User entered '4'	System	08 Apr 2021 19:54:59
User entered '3'	System	06 Apr 2021 13:41:45
User entered '2'	System	05 Apr 2021 16:36:00
User entered '1'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 15:10:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 21:55:45
User entered '08/Apr/2021 12:54'	(b) (4) System	08 Apr 2021 19:54:59

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 15:10:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
User signature succeeded.	Mark Hutchens (b) (4)	08 Apr 2021 21:55:45
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 19:54:59

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'USA-US211-2021-MRNA-1273-P301000003'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Yes (Y)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'No (N)'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Mark'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'Hutchens'	System	26 Mar 2021 18:45:04

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:00:10
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:22:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:45:22
User entered 'US'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:10:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 13:23:23
User entered '4'	System	08 Apr 2021 19:54:59
User entered '3'	System	06 Apr 2021 13:41:45
User entered '2'	System	05 Apr 2021 16:36:00
User entered '1'	System	26 Mar 2021 18:45:19

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 15:10:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
User signature succeeded.	Mark Hutchens (b) (4)	13 Apr 2021 13:51:36
User entered '13/Apr/2021 06:23'	(b) (4) System	13 Apr 2021 13:23:23

US3912046

Folder: SAE USA-US211-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 15:10:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:54:12
User signature succeeded.	Mark Hutchens (b) (4)	13 Apr 2021 13:51:36
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 13:23:23