

US3812010 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:50:16

All time stamps listed in this document are displayed in GMT

US3812010

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Participant ID

US3812010

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

US3812010

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3812010

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
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

US3812010

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Date of Informed Consent (*dd MMM yyyy*) 03 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3812010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3812010

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Were any significant conditions reported?

Yes ☒

No ☐

US3812010

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3812010

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812010

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3812010

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3812010

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	LEFT ROTATOR CUFF STRAIN
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3812010

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3812010

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	BILATERAL KNEE PAIN
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3812010

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	ELEVATED CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3812010

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	BILATERAL KNEE OSTEOARTHRITIS
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)	

US3812010

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	BILATERAL SHOULDER OSTEOARTHRITIS
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)	_____

US3812010

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	WEEKLY CIGAR SMOKER
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3812010

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	BPH
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812010

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	RECURRENT DIVERTICULITIS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3812010

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Condition	BILATERAL LOWER EXTREMITY SENSORY DIABETIC NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3812010

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:15 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 11:15
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	222 lb
BMI (<i>xxx.x</i>)	32.85222 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)	

US3812010

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 AUG 2020

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

US3812010

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 04:01:18

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3812010

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 184473

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 ☐

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Height	ND - Not Done
Weight	ND - Not Done

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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)	03 AUG 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 11:15
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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)	03 AUG 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 13:15
Temperature (xxx.x)	97.5 F
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812010

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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.

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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) 03 AUG 2020

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 03 AUG 2020 12:45

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

US3812010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 AUG 2020
Collection time (00:00-23:59)	12:38 (24 HR)
Collection date and time (derived)	03 AUG 2020 12:38

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Collection date (dd MMM yyyy)			03 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:40	03 AUG 2020 12:40
Nasopharyngeal Swab 2	No		

US3812010

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

97.5 °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

03 AUG 2020 13:18

PC Open Date & Time

03 AUG 2020 13:05

PC Close Date & Time

03 AUG 2020 15:35

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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 97.4 °F

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

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

PC Time Stamp	03 AUG 2020 16:49
PC Open Date & Time	03 AUG 2020 16:30
PC Close Date & Time	04 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 13:07

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

98.0 °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

05 AUG 2020 14:32

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

98.7 °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

06 AUG 2020 15:08

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

97.5 °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

07 AUG 2020 13:46

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

96.6 °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

08 AUG 2020 22:57

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

98.5 °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

09 AUG 2020 16:50

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

03 AUG 2020 13:19

PC Open Date & Time

03 AUG 2020 13:05

PC Close Date & Time

03 AUG 2020 15:35

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

03 AUG 2020 16:50

PC Open Date & Time

03 AUG 2020 16:30

PC Close Date & Time

04 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

10

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 14:42

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

55

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 14:33

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 15:08

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

07 AUG 2020 13:47

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

08 AUG 2020 22:58

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

09 AUG 2020 16:50

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 AUG 2020 13:05

PC Close Date & Time

03 AUG 2020 15:35

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 16:52
PC Open Date & Time	03 AUG 2020 16:30
PC Close Date & Time	04 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

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
EAB) (1725)

58 of 2534

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 14:43
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

60 of 2534

EAB) (1725)

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 14:33
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

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 ☒

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 15:09
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

64 of 2534

EAB) (1725)

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 13:47
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

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 ☒

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 22:59
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

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 ☒

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 16:51
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3812010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	VISIT2

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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 AUG 2020
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 08:06
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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)	28 AUG 2020
Time of assessment (00:00-23:59)	09:56 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 09:56
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 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)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3812010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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 AUG 2020

What was the treatment time? (00:00-23:59) 09:21 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 09:21

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

US3812010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

09:14 (24 HR)

Collection date and time (derived)

28 AUG 2020 09:14

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:17	28 AUG 2020 09:17
Nasopharyngeal Swab 2	No		

US3812010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 09:59

PC Open Date & Time

28 AUG 2020 09:41

PC Close Date & Time

28 AUG 2020 12:11

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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 98.0 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 AUG 2020 22:11

PC Open Date & Time 28 AUG 2020 13:06

PC Close Date & Time 29 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

100.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 12:28

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	30 AUG 2020 13:36
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 16:30

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

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 SEP 2020 10:21

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

28 AUG 2020 10:01

PC Open Date & Time

28 AUG 2020 09:41

PC Close Date & Time

28 AUG 2020 12:11

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

6

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

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

28 AUG 2020 22:12

PC Open Date & Time

28 AUG 2020 13:06

PC Close Date & Time

29 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:29

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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 ☐

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

10

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

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

Yes ☒

No ☐

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

10

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 13:38

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 16:31

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:16

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 10:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

03 SEP 2020 15:06

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 10:01
PC Open Date & Time	28 AUG 2020 09:41
PC Close Date & Time	28 AUG 2020 12:11

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 22:12
PC Open Date & Time	28 AUG 2020 13:06
PC Close Date & Time	29 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

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 ☒

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:31
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

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 ☒

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 13:39
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

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 ☒

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 16:32
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

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)

110 of 2534

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

112 of 2534

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 10:22
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

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 ☒

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 15:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3812010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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)	09:25 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:25
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)	63 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)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

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.

US3812010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

28 SEP 2020 09:40

US3812010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 OCT 2020 05:13:35

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

11 OCT 2020 14:25:51

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

17 OCT 2020 06:17:59

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 OCT 2020 08:56:28
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 99
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 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"/>
Have 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	09 NOV 2020 12:33:58
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 106
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	14 NOV 2020 00:01:48
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 11:15:27

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 09:04:33

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	04 DEC 2020 08:55:02
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

09 DEC 2020 07:49:02

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

18 DEC 2020 08:21:38

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

23 DEC 2020 00:04:01

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 DEC 2020 08:54:11
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 <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	08 JAN 2021 12:01:50
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 07:25:03

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 08:19:53

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 15:35:40
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

04 FEB 2021 11:12:47

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

11 FEB 2021 18:19:08

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 FEB 2021 05:22:11

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 20:26:21

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 09:38:38

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

10 MAR 2021 08:26:30

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

17 MAR 2021 15:41:26

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

26 MAR 2021 08:12:32

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

03 APR 2021 10:06:30

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 09:35:02

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 07:01:58

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	22 APR 2021 14:33:47
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Date and time of submission

28 APR 2021 04:48:23

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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°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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Patient Cloud Open Date & Time	13 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

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06 FEB 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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13 FEB 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

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27 FEB 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

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06 MAR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

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20 MAR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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27 MAR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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="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"/>

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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°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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3812010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:50:16

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		06 MAR 2021 09:38:53

US3812010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:01:17

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

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

Visit date (dd MMM yyyy)	01 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:47:21

Generated On: 10 Jun 2021 09:50:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 09:00
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 MAR 2021

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

US3812010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 01 MAR 2021

Collection time (00:00-23:59) 09:25 (24 HR)

Collection date and time (derived) 01 MAR 2021 09:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted?

Yes ☐

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:23:59

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812010

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812010

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 15:34:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 15:34:58

Generated On: 10 Jun 2021 09:50:16

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☐

US3812010

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

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

Visit date (dd MMM yyyy)	18 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3812010

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

Date of updated informed consent (dd MMM yyyy) 18 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3812010

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

12:40 (24 HR)

Collection date and time (derived)

18 JAN 2021 12:40

US3812010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	12:45
Collection Date and Time (derived)	18 JAN 2021 12:45

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Visit Date	14 AUG 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:20 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 14:20
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:01:18

Generated On: 10 Jun 2021 09:50:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3812010

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 04:01:13

Generated On: 10 Jun 2021 09:50:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID

Adverse event

NON-URTICARIAL
MACULOPAPULAR RASH TO
LEFT UPPER ARM (BELOW
INJECTION SITE)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 AUG 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 ☐

PRODUCTION RELEASE (v12.003

337 of 2534

EAB) (1725)

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID	
Adverse event	NECK PAIN
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)	12 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 AUG 2020
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"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

339 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID	USA-US111-2020-MRNA-1273-P30 1000024
Adverse event	UNSTABLE ANGINA
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)	23 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	28 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

THE SUBJECT IS A
71-YEAR-OLD MALE WITH A
HISTORY OF TYPE TWO
DIABETES, HYPERTENSION,
HYPERLIPIDEMIA,
GASTROESOPHAGEAL REFLUX
DISEASE, AND OBSTRUCTIVE
SLEEP APNEA WHO PRESENTED
TO THE EMERGENCY
DEPARTMENT ON 26
DECEMBER 2020 WITH A
THREE DAY HISTORY OF
EXERTIONAL SHORTNESS OF
BREATH AND CHEST
TIGHTNESS. HE PRESENTED TO
THE EMERGENCY
DEPARTMENT WHEN HE
BEGAN TO EXPERIENCE
SHORTNESS OF BREATH AND
CHEST TIGHTNESS AT REST.
CHEST X-RAY WAS
UNREMARKABLE. ECG
SHOWED RIGHT BUNDLE
BRANCH BLOCK CONSISTENT
WITH A PRIOR ECG. RESTING
ECHOCARDIOGRAPHY WAS
UNREMARKABLE. STRESS
ECHOCARDIOGRAM WAS
POSITIVE FOR MYOCARDIAL
ISCHEMIA IN THE MID-LEFT
ANTERIOR DESCENDING
ARTERY DISTRIBUTION
ACCOMPANIED BY ANGINAL
CHEST PAIN AND A
HYPERTENSIVE RESPONSE TO

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

EXERCISE. HE WAS
DISCHARGED ON 28DEC2020
FROM HOSPITAL. ON 04JAN21
SUBJECT REPORTED TO
OUTPATIENT CARDIAC
CATHETERIZATION LAB, AND
UNDERWENT RIGHT AND LEFT
CORONARY ANGIOGRAPHY,
INTRAVASCULAR
ULTRASOUND OF THE LEFT
ANTERIOR DESCENDING
ARTERY, AND PERCUTANEOUS
INTERVENTION WITH A DRUG
ELUTING STENT PLACED INTO
THE LEFT ANTERIOR
DESCENDING CORONARY
ARTERY. HE WAS FOUND TO
HAVE A 99% MID-LEFT
ANTERIOR DESCENDING
ARTERY LESION AND A 70%
PROXIMAL LEFT ANTERIOR
DESCENDING CORONARY
ARTERY LESION. BOTH
LESIONS WERE STENTED. HE
WAS STARTED ON
CLOPIDOGREL 75 MG DAILY
AND CONTINUED THERAPY
WITH ONE BABY ASPIRIN
DAILY. TROPONINS STAYED
WITHIN THE NORMAL RANGE.
BRAIN NATRIURETIC PEPTIDE
WAS NORMAL (5 PG/ML, REF
<OR = 300).

THIS IS

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

BEEN REPORTED AS A SERIOUS
ADVERSE EVENT DUE TO
BEING AN IMPORTANT
MEDICAL EVENT AND, GIVEN
THE SEVERITY OF HIS
CORONARY ARTERY LESIONS,
WOULD LIKELY HAVE BEEN
FATAL WITHOUT
INTERVENTION.

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

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID	
Adverse event	CORONARY ARTERY DISEASE
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)	04 JAN 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____ _____	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID	
Adverse event	HYPERTENSION
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)	04 JAN 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"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID	
Adverse event	WORSENING GASTROESOPHAGEAL REFLUX DISEASE
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)	15 FEB 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID	
Adverse event	ALLERGIC REACTION TO LISINOPRIL
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)	15 FEB 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

AEID

Adverse event

BILATERAL EAR PAIN

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)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

354 of 2534

EAB) (1725)

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 00:45:10

Generated On: 10 Jun 2021 09:50:16

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

Yes ☒

No ☐

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

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1977	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

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)

359 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication ELEVATED CHOLESTEROL

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	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 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration .4

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)

363 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHE, JOINT ACHES,
HEADACHE, FEVER, &
INJECTION SITE PAIN

Dose per administration 600

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)

365 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication UNSTABLE ANGINA AND CAD

Dose per administration 80

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)

367 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 DEC 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"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication PLAVIX

Prophylaxis Yes ☐
No ☒

Indication UNSTABLE ANGINA AND CAD

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 DEC 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"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication ISOSORBIDE/MONONITRATE ER

Prophylaxis Yes ☐
No ☒

Indication UNSTABLE ANGINA AND CAD

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 DEC 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"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication UNSTABLE ANGINA AND CAD

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 DEC 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"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication UNSTABLE ANGINA AND CAD

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
EAB) (1725)

375 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 DEC 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"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication LISINOPRIL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	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)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 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"/>

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING
GASTROESOPHAGEAL REFLUX
DISEASE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

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

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC REACTION TO
LISINOPRIL

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 15:17:58

Generated On: 10 Jun 2021 09:50:16

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 APR 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"/>

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 19:42:31

Generated On: 10 Jun 2021 09:50:16

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 19:42:30

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 DEC 2020	CHEST X-RAY	Adverse Event	
26 DEC 2020	ECG	Adverse Event	
26 DEC 2020	RESTING ECHOCARDIOGRAPHY	Adverse Event	
26 DEC 2020	STRESS ECHOCARDIOGRAM	Adverse Event	
04 JAN 2021	CARDIAC ECHOCARDIOGRAM	Adverse Event	
04 JAN 2021	PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT	Adverse Event	
04 JAN 2021	LEFT CORONARY ANGIOGRAPHY	Adverse Event	
04 JAN 2021	RIGHT CORONARY ANGIOGRAPHY	Adverse Event	
26 DEC 2020	CHEST, ABDOMINAL, AND PELVIC COMPUTERIZED TOMOGRAPHY ANGIOGRAPHY	Adverse Event	

US3812010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:50:16

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3812010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:50:16

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 ☐

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 16:25:42

Generated On: 10 Jun 2021 09:50:16

SAEID	USA-US111-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 16:25:42

Generated On: 10 Jun 2021 09:50:16

SAEID	USA-US111-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/DEC/2020 11:19
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

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 16:25:42

Generated On: 10 Jun 2021 09:50:16

SAEID	USA-US111-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/JAN/2021 21:24
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

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 16:25:42

Generated On: 10 Jun 2021 09:50:16

SAEID	USA-US111-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/JAN/2021 13:30
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

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 16:25:42

Generated On: 10 Jun 2021 09:50:16

SAEID	USA-US111-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/MAR/2021 11:26
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

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 16:25:42

Generated On: 10 Jun 2021 09:50:16

SAEID	USA-US111-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/MAR/2021 12:12
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

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 16:25:42

Generated On: 10 Jun 2021 09:50:16

SAEID	USA-US111-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/APR/2021 09:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3812010 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812010

Form: Participant Creation

Generated On: 10 Jun 2021 09:50:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'US3812010'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:14:16

US3812010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Heather Cherniawski	03 Aug 2020 18:03:22

US3812010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:14:17

US3812010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Clinic (Clinic)'	Heather Cherniawski	03 Aug 2020 18:03:22

US3812010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'SCRN'	System	03 Aug 2020 18:03:22

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:14:17

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '71'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'YEARS'	System	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '71'	System	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Male (M)'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'I'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:50:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Megan Dandurand (b) (4)	04 Aug 2020 21:55:57

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 18:48:56
User entered '3 Aug 2020'	Heather Cherniawski	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Aug 2020'	System	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2020'	System	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Amendment 1 (1)'	Heather Cherniawski	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Heather Cherniawski	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:03:53

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:14:17

US3812010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:50:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'I'	System	03 Aug 2020 18:03:59

US3812010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Heather Cherniawski	03 Aug 2020 18:03:59

US3812010

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:50:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Please complete prior conmeds page as medical history lists history as ongoing.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:54:50
Query 'Please complete prior conmeds page as medical history lists history as ongoing.' answered with 'COMPLETED' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 03:18:28
User opened query 'Please complete prior conmeds page as medical history lists history as ongoing.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:23:50
User closed query 'Please complete the prior conmed page. Thank you' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 14:15:06
Query 'Please complete the prior conmed page. Thank you' answered with 'updated per source' (Site from CRA).	Anya Penly (b) (4) (b) (4)	09 Sep 2020 19:29:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	09 Sep 2020 19:29:05
User opened query 'Please complete the prior conmed page. Thank you' (Site from CRA).	(b) (4), (b) (6)	08 Sep 2020 23:47:22
User entered 'No (N)'	Megan Dandurand (b) (4) (b) (4)	04 Aug 2020 21:56:36

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:31:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:31:48
Data point term sent to Coder	System	09 Sep 2020 19:30:28
User entered 'sleep apnea'	Any Penly (b) (4)	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2000'	Any Penly (b) (4)	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2000'	System	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2000'	System	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:29:35

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:31:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:31:48
Data point term sent to Coder	System	09 Sep 2020 19:30:30
User entered 'GERD'	Any Penly (b) (4)	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 1977'	Any Penly (b) (4)	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 1977'	System	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '1977'	System	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:29:52

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Per DM CLR: Please specify the ear laterality with HEARING LOSS (Left, Right or Bilateral). Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 12:30:34
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:51:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:51:36
Data point term sent to Coder	System	14 Oct 2020 19:50:50
Query 'Per DM CLR: Please specify the ear laterality with HEARING LOSS (Left, Right or Bilateral). Review and update Med History eCRF as appropriate. ' answered with 'UPDATED PER SOURCE' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:50:32
Coding entries removed.	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:50:18
User entered 'BILATERAL HEARING LOSS' reason for change: Per Query Resolution	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:50:18
User opened query 'Per DM CLR: Please specify the ear laterality with HEARING LOSS (Left, Right or Bilateral). Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:10:05
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 19:32:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 19:32:16
Data point term sent to Coder	System	09 Sep 2020 19:30:32
User entered 'hearing loss'	Any Penly (b) (4) (b) (4)	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 1995'	Any Penly (b) (4)	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 1995'	System	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '1995'	System	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:30:15

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 11:56:40
Query 'Per DM CLR: Please note that there is no Con Maureen Dempsey Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'METFORMIN IS LISTED IN CONMEDS FOR THIS CONDITION ' (Site from DM).	(b) (4) (b) (4)	14 Oct 2020 19:52:21
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:09:53
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 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 19:32:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 19:32:42
Data point term sent to Coder	System	09 Sep 2020 19:31:36
User entered 'diabetes type 2'	Anya Penly (b) (4) (b) (4)	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2010'	Any Penly (b) (4)	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2010'	System	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2010'	System	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:30:35

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff injury - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:35:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:35:33
Data point term sent to Coder	System	09 Sep 2020 19:40:00
User entered 'left rotator cuff strain'	Any Penly (b) (4)	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2004'	Any Penly (b) (4)	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Any Penly (b) (4)	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2005'	Any Penly (b) (4)	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2004'	System	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2004'	System	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2005'	System	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2005'	System	09 Sep 2020 19:39:37

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:41:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:41:48
Data point term sent to Coder	System	09 Sep 2020 19:41:01
User entered 'left rotator cuff repair'	Any Penly (b) (4)	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2005'	Any Penly (b) (4)	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Any Penly (b) (4)	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2005'	Any Penly (b) (4)	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2005'	System	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2005'	System	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2005'	System	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2005'	System	09 Sep 2020 19:40:12

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:41:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:41:49
Data point term sent to Coder	System	09 Sep 2020 19:41:05
User entered 'bilateral meniscus repair'	Any Penly (b) (4)	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2013'	Any Penly (b) (4)	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Any Penly (b) (4)	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2013'	Any Penly (b) (4)	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2013'	System	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2013'	System	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2013'	System	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2013'	System	09 Sep 2020 19:40:35

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:41:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:41:48
Data point term sent to Coder	System	09 Sep 2020 19:41:05
User entered 'bilateral knee pain'	Any Penly (b) (4)	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2007'	Any Penly (b) (4)	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Any Penly (b) (4)	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2013'	Any Penly (b) (4)	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2007'	System	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2007'	System	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2013'	System	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2013'	System	09 Sep 2020 19:40:59

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Investigations, HLGt: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Cholesterol high - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:42:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:42:52
Data point term sent to Coder	System	09 Sep 2020 19:42:08
User entered 'elevated cholesterol'	Any Penly (b) (4)	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'UN UNK 2001' reason for change: Per Query Resolution	Angie Kean (b) (4)	26 Oct 2020 21:13:39
User entered 'un UNK 2010'	Anya Penly (b) (4)	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2001'	System	26 Oct 2020 21:13:39
User entered 'Jan 2010'	System	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2001'	System	26 Oct 2020 21:13:39
User entered '2010'	System	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:41:16

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:42:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:42:52
Data point term sent to Coder	System	09 Sep 2020 19:42:08
User entered 'bilateral knee osteoarthritis'	Any Penly (b) (4)	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2014'	Any Penly (b) (4)	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2014'	System	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2014'	System	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:41:36

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:42:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:42:52
Data point term sent to Coder	System	09 Sep 2020 19:42:09
User entered 'bilateral shoulder osteoarthritis'	Any Penly (b) (4)	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2014'	Any Penly (b) (4)	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2014'	System	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2014'	System	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:41:53

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Social circumstances, HLT: Tobacco use, PT: Tobacco user, LLT: Cigar smoker - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 06:01:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 06:01:49
Data point term sent to Coder	System	09 Sep 2020 19:44:14
User entered 'weekly cigar smoker'	Any Penly (b) (4)	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un Jan 2020'	Any Penly (b) (4)	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2020'	System	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2020'	System	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:44:01

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:45:45
Data point term sent to Coder	System	09 Sep 2020 19:45:17
User entered 'fatty liver'	Any Penly (b) (4)	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2010'	Any Penly (b) (4)	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2010'	System	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2010'	System	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:44:20

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:45:45
Data point term sent to Coder	System	09 Sep 2020 19:45:16
User entered 'BPH'	Any Penly (b) (4)	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2019'	Any Penly (b) (4)	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2019'	System	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2019'	System	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:44:36

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:45:45
Data point term sent to Coder	System	09 Sep 2020 19:45:17
User entered 'recurrent diverticulitis'	Any Penly (b) (4)	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2019'	Any Penly (b) (4)	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Any Penly (b) (4)	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2019'	Any Penly (b) (4)	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2019'	System	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2019'	System	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2019'	System	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2019'	System	09 Sep 2020 19:45:00

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:26:20
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) (b) (4)	03 Nov 2020 08:24:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 08:24:15
Data point term sent to Coder	System	02 Nov 2020 18:08:36
Query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated per investigator' (Site from DM).	Anya Penly (b) (4) (b) (4)	02 Nov 2020 18:08:08
Coding entries removed.	Anya Penly (b) (4) (b) (4)	02 Nov 2020 18:07:55
User entered 'BILATERAL LOWER EXTREMITY sensory DIABETIC NEUROPATHY' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	02 Nov 2020 18:07:55
User opened query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:38:47

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

Condition

Audit	User	Time (GMT)
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) (b) (4)	10 Sep 2020 00:01:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:01:51
Data point term sent to Coder	System	09 Sep 2020 19:46:18
User entered 'Bilateral lower extremity diabetic neuropathy'	Any Penly (b) (4) (b) (4)	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2019'	Any Penly (b) (4)	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Any Penly (b) (4)	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Any Penly (b) (4)	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2019'	System	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2019'	System	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered empty.	System	09 Sep 2020 19:45:29

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:48:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 19:48:48
Data point term sent to Coder	System	09 Sep 2020 19:47:21
User entered 'bilateral meniscus tear'	Any Penly (b) (4)	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2013'	Any Penly (b) (4)	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Any Penly (b) (4)	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'un UNK 2013'	Any Penly (b) (4)	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Any Penly (b) (4)	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2013'	System	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2013'	System	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'Jan 2013'	System	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '2013'	System	09 Sep 2020 19:46:24

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 18:49:38
User entered '3 Aug 2020'	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '11:15'	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered '03 Aug 2020 11:15'	System	10 Nov 2020 18:49:38
User entered '3 Aug 2020 11:15'	System	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '69' in	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29
DataPoint set to visible.	System	03 Aug 2020 18:03:59

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '222' lb	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29
DataPoint set to visible.	System	03 Aug 2020 18:03:59

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
Amendment Manager: User entered '32.85222'	System	16 Sep 2020 23:41:21
User entered '32.9'	System	04 Aug 2020 21:57:29
DataPoint set to visible.	System	03 Aug 2020 18:03:59

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'kg/m2'	System	04 Aug 2020 21:57:29
DataPoint set to visible.	System	03 Aug 2020 18:03:59

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Aug 2020 09:37:44
Query 'Data is required. Please provide.' answered with 'per EDC guidelines pre-dose temperature recorded in another folder.' (Site from System).	Anya Penly (b) (4) (b) (4)	06 Aug 2020 13:16:01
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Aug 2020 21:57:29
User entered empty.	Megan Dandurand (b) (4) (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'bpm'	System	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'breaths/min'	System	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'mmHg'	System	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User entered 'mmHg'	System	04 Aug 2020 21:57:29

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18

US3812010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18

US3812010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 22:15:47
User closed query 'Please confirm if Physical exam was performed.' (Site from CRA).	(b) (4), (b) (6)	08 Sep 2020 19:17:21
Query 'Please confirm if Physical exam was performed.' answered with 'PHYSICAL EXAM WAS PERFORMED AT SCREEN/VISIT 1. HOWEVER AUTO GENERATED QUERY SAYS The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile. TO REMOVE QUERY CHANGED TO NO IN SCREEN AND YES IN VISIT1.' (Site from CRA).	Karen Knapp (b) (4)	07 Sep 2020 18:47:12
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	07 Sep 2020 18:47:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Knapp (b) (4)	07 Sep 2020 18:45:47
User opened query 'Please confirm if Physical exam was performed.' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 20:13:05
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	01 Sep 2020 18:55:27
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 21:58:35

US3812010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 03:20:49
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 03:20:49
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 22:15:47
User entered '3 Aug 2020' reason for change: Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 22:15:47
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	07 Sep 2020 18:47:04
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	07 Sep 2020 18:47:04
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	07 Sep 2020 18:45:47
User entered '3 Aug 2020' reason for change: Data Entry Error	Karen Knapp (b) (4)	07 Sep 2020 18:45:47
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 18:55:27
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	01 Sep 2020 18:55:27
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 14:48:37
User entered '3 Aug 2020'	Megan Dandurand (b) (4)	04 Aug 2020 21:58:35

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski (b) (4)	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

[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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

[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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

[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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'I'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Heather Cherniawski (b) (4)	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Heather Cherniawski (b) (4)	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

[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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '0'	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:50:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:18
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski	03 Aug 2020 18:05:46

US3812010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 21:58:53

US3812010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 18:49:55
User entered '3 Aug 2020'	(b) (4)	
	Megan Dandurand (b) (4)	04 Aug 2020 21:58:53
	(b) (4)	

US3812010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Clinic (Clinic)'	Megan Dandurand (b) (4)	04 Aug 2020 21:58:53

US3812010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'VISIT1'	System	04 Aug 2020 21:58:53

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:14:18

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:46:12
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:46:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 17:14:18
User entered '184473' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:14:18

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:14:18

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

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)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Megan Dandurand (b) (4)	04 Aug 2020 21:59:21

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

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)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Megan Dandurand (b) (4)	04 Aug 2020 21:59:21

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Megan Dandurand (b) (4)	04 Aug 2020 21:59:21

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 21:59:21

US3812010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:50:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 21:59:21

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Pre-Dose (PREDOSE)'	Megan Dandurand (b) (4) (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 18:50:11
User entered '3 Aug 2020'	(b) (4)	
	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15
	(b) (4)	

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '11:15'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '03 Aug 2020 11:15'	System	10 Nov 2020 18:50:11
User entered '3 Aug 2020 11:15'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '97.1' F	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Oral (Oral)'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '64'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'bpm'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '14'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'breaths/min'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '124'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '72'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:50:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered missing code ND - Not Done.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Post-Dose (POSTDOSE)'	Megan Dandurand (b) (4) (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 18:50:11
User entered '3 Aug 2020'	(b) (4)	
	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15
	(b) (4)	

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Aug 2020 10:21:19
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DM error' (Site from System).	Anya Penly (b) (4) (b) (4)	06 Aug 2020 15:07:03
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 22:02:15
User entered '13:15'	Megan Dandurand (b) (4) (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '03 Aug 2020 13:15'	System	10 Nov 2020 18:50:11
User entered '3 Aug 2020 13:15'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '97.5' F	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Oral (Oral)'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '73'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'bpm'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '12'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'breaths/min'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '125'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '72'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	04 Aug 2020 22:02:15

US3812010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 22:16:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Knapp (b) (4)	07 Sep 2020 18:45:17
User entered 'No (N)'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:31

US3812010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 22:16:00
User entered '3 Aug 2020' reason for change: Data Entry Error	Karen Knapp (b) (4)	07 Sep 2020 18:45:17
User entered empty.	Megan Dandurand (b) (4)	04 Aug 2020 22:02:31

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Heather Cherniawski	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski (b) (4)	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski (b) (4)	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 18:50:26
User entered '3 Aug 2020'	(b) (4)	
	Heather Cherniawski	03 Aug 2020 18:07:30
	(b) (4)	

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '12:45'	Heather Cherniawski	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '03 Aug 2020 12:45'	System	10 Nov 2020 18:50:26
User entered '3 Aug 2020 12:45'	System	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'ONCE'	System	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 18:07:30

US3812010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:58

US3812010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 18:50:34
User entered '3 Aug 2020'	(b) (4)	
	Megan Dandurand (b) (4)	04 Aug 2020 22:02:58
	(b) (4)	

US3812010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '12:38'	Megan Dandurand (b) (4)	04 Aug 2020 22:02:58

US3812010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '03 Aug 2020 12:38'	System	10 Nov 2020 18:50:34
User entered '3 Aug 2020 12:38'	System	04 Aug 2020 22:02:58

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:50:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 18:50:41
User entered '3 Aug 2020'	(b) (4)	
	Megan Dandurand (b) (4)	04 Aug 2020 22:03:21
	(b) (4)	

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Megan Dandurand (b) (4) (b) (4)	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '12:40'	Megan Dandurand (b) (4)	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '03 Aug 2020 12:40'	System	10 Nov 2020 18:50:41
User entered '3 Aug 2020 12:40'	System	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Megan Dandurand (b) (4) (b) (4)	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Megan Dandurand (b) (4)	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Megan Dandurand (b) (4)	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered empty.	System	04 Aug 2020 22:03:21

US3812010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	04 Aug 2020 22:03:35

US3812010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	04 Aug 2020 22:03:35

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:17:52', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f3e9d09c-fffb-4732-b85a-ad5fa3b5caac'	System	03 Aug 2020 18:18:27
User entered 'Yes (Y)'	System	03 Aug 2020 18:18:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:18:04', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f3e9d09c-fffb-4732-b85a-ad5fa3b5caac' User entered '97.5'	System	03 Aug 2020 18:18:27
	System	03 Aug 2020 18:18:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:18:13', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f3e9d09c-fffb-4732-b85a-ad5fa3b5caac'	System	03 Aug 2020 18:18:27
User entered 'No (N)'	System	03 Aug 2020 18:18:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:18:24', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f3e9d09c-fffb-4732-b85a-ad5fa3b5caac'	System	03 Aug 2020 18:18:27
User entered '03 Aug 2020 13:18'	System	03 Aug 2020 18:18:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 13:05'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 15:35'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:49:02', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ae03e149-6d4d-43a0-98a6-80280c641bda' User entered 'Yes (Y)'	System	03 Aug 2020 21:49:26
	System	03 Aug 2020 21:49:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:49:13', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ae03e149-6d4d-43a0-98a6-80280c641bda' User entered '97.4'	System	03 Aug 2020 21:49:26
	System	03 Aug 2020 21:49:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:49:17', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ae03e149-6d4d-43a0-98a6-80280c641bda' User entered 'No (N)'	System	03 Aug 2020 21:49:26
	System	03 Aug 2020 21:49:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:49:24', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ae03e149-6d4d-43a0-98a6-80280c641bda' User entered '03 Aug 2020 16:49'	System	03 Aug 2020 21:49:26
	System	03 Aug 2020 21:49:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 16:30'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 2'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T13:06:48', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5f518b37-c070-4bde-9c7b-9f0f368bd2f3' User entered 'Yes (Y)'	System	04 Aug 2020 18:07:16
	System	04 Aug 2020 18:07:16

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T13:06:54', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5f518b37-c070-4bde-9c7b-9f0f368bd2f3' User entered '97.8'	System	04 Aug 2020 18:07:16
	System	04 Aug 2020 18:07:16

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T13:07:01', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5f518b37-c070-4bde-9c7b-9f0f368bd2f3'	System	04 Aug 2020 18:07:16
User entered 'No (N)'	System	04 Aug 2020 18:07:16

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T13:07:12', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5f518b37-c070-4bde-9c7b-9f0f368bd2f3'	System	04 Aug 2020 18:07:16
User entered '04 Aug 2020 13:07'	System	04 Aug 2020 18:07:16

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 3'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:32:37', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '9172be59-5ce3-457b-9173-48b8224bd5ad' User entered 'Yes (Y)'	System	05 Aug 2020 19:33:00
	System	05 Aug 2020 19:33:00

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:32:45', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '9172be59-5ce3-457b-9173-48b8224bd5ad' User entered '98.0'	System	05 Aug 2020 19:33:00
	System	05 Aug 2020 19:33:00

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:32:49', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '9172be59-5ce3-457b-9173-48b8224bd5ad'	System	05 Aug 2020 19:33:00
User entered 'No (N)'	System	05 Aug 2020 19:33:00

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:32:58', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '9172be59-5ce3-457b-9173-48b8224bd5ad' User entered '05 Aug 2020 14:32'	System	05 Aug 2020 19:33:00
	System	05 Aug 2020 19:33:00

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 4'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:07:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '31dfee1a-bb92-4b72-80c4-a70350392338' User entered 'Yes (Y)'	System	06 Aug 2020 20:08:26
	System	06 Aug 2020 20:08:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:12', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '31dfee1a-bb92-4b72-80c4-a70350392338' User entered '98.7'	System	06 Aug 2020 20:08:26
	System	06 Aug 2020 20:08:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:17', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '31dfee1a-bb92-4b72-80c4-a70350392338'	System	06 Aug 2020 20:08:26
User entered 'No (N)'	System	06 Aug 2020 20:08:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:24', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '31dfee1a-bb92-4b72-80c4-a70350392338' User entered '06 Aug 2020 15:08'	System	06 Aug 2020 20:08:26
	System	06 Aug 2020 20:08:26

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 5'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:46:23', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ff04d3e5-f935-4511-8971-ecddb2f62b80' User entered 'Yes (Y)'	System	07 Aug 2020 18:46:43
	System	07 Aug 2020 18:46:43

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:46:30', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ff04d3e5-f935-4511-8971-ecddb2f62b80' User entered '97.5'	System	07 Aug 2020 18:46:43
	System	07 Aug 2020 18:46:43

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:46:35', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ff04d3e5-f935-4511-8971-ecddb2f62b80'	System	07 Aug 2020 18:46:43
User entered 'No (N)'	System	07 Aug 2020 18:46:43

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:46:42', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ff04d3e5-f935-4511-8971-ecddb2f62b80'	System	07 Aug 2020 18:46:43
User entered '07 Aug 2020 13:46'	System	07 Aug 2020 18:46:43

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 6'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:57:11', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '032810d4-4505-46e1-ace7-d32a17789db5' User entered 'Yes (Y)'	System	09 Aug 2020 03:57:49
	System	09 Aug 2020 03:57:49

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:57:18', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '032810d4-4505-46e1-ace7-d32a17789db5' User entered '96.6'	System	09 Aug 2020 03:57:49
	System	09 Aug 2020 03:57:49

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:57:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '032810d4-4505-46e1-ace7-d32a17789db5' User entered 'No (N)'	System	09 Aug 2020 03:57:49
	System	09 Aug 2020 03:57:49

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:57:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '032810d4-4505-46e1-ace7-d32a17789db5' User entered '08 Aug 2020 22:57'	System	09 Aug 2020 03:57:49
	System	09 Aug 2020 03:57:49

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 7'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:14', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '83b2ccd2-42ea-4427-9d62-5364d170b902'	System	09 Aug 2020 21:50:27
User entered 'Yes (Y)'	System	09 Aug 2020 21:50:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:18', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '83b2ccd2-42ea-4427-9d62-5364d170b902'	System	09 Aug 2020 21:50:27
User entered '98.5'	System	09 Aug 2020 21:50:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '83b2ccd2-42ea-4427-9d62-5364d170b902'	System	09 Aug 2020 21:50:27
User entered 'No (N)'	System	09 Aug 2020 21:50:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:26', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '83b2ccd2-42ea-4427-9d62-5364d170b902'	System	09 Aug 2020 21:50:27
User entered '09 Aug 2020 16:50'	System	09 Aug 2020 21:50:27

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:18:35', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b6983af8-1111-4de6-8229-4e62e3ab3fe9' User entered 'None (1)'	System	03 Aug 2020 18:19:25
	System	03 Aug 2020 18:19:25

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:18:55', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b6983af8-1111-4de6-8229-4e62e3ab3fe9' User entered 'No (N)'	System	03 Aug 2020 18:19:25
	System	03 Aug 2020 18:19:25

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:18:59', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b6983af8-1111-4de6-8229-4e62e3ab3fe9' User entered 'No (N)'	System	03 Aug 2020 18:19:25
	System	03 Aug 2020 18:19:25

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:19:15', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b6983af8-1111-4de6-8229-4e62e3ab3fe9' User entered 'None (1)'	System	03 Aug 2020 18:19:25
	System	03 Aug 2020 18:19:25

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T13:19:20', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b6983af8-1111-4de6-8229-4e62e3ab3fe9' User entered '03 Aug 2020 13:19'	System	03 Aug 2020 18:19:25
	System	03 Aug 2020 18:19:25

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 13:05'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 15:35'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:49:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '13462e88-3278-47c9-a625-5fb52fc4a8b1' User entered 'Does not interfere with activity (2)'	System	03 Aug 2020 21:50:42
	System	03 Aug 2020 21:50:42

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:49:51', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '13462e88-3278-47c9-a625-5fb52fc4a8b1' User entered 'No (N)'	System	03 Aug 2020 21:50:42
	System	03 Aug 2020 21:50:42

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:50:26', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '13462e88-3278-47c9-a625-5fb52fc4a8b1' User entered 'No (N)'	System	03 Aug 2020 21:50:42
	System	03 Aug 2020 21:50:42

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:50:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '13462e88-3278-47c9-a625-5fb52fc4a8b1' User entered 'None (1)'	System	03 Aug 2020 21:50:42
	System	03 Aug 2020 21:50:42

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:50:39', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '13462e88-3278-47c9-a625-5fb52fc4a8b1' User entered '03 Aug 2020 16:50'	System	03 Aug 2020 21:50:42
	System	03 Aug 2020 21:50:42

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 16:30'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 2'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:41:59', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0b131b0d-6cd5-47e5-9720-87477702bc6f' User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 19:42:33
	System	04 Aug 2020 19:42:33

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:03', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0b131b0d-6cd5-47e5-9720-87477702bc6f' User entered 'No (N)'	System	04 Aug 2020 19:42:33
	System	04 Aug 2020 19:42:33

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:07', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0b131b0d-6cd5-47e5-9720-87477702bc6f' User entered 'Yes (Y)'	System	04 Aug 2020 19:42:33
	System	04 Aug 2020 19:42:33

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:14', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0b131b0d-6cd5-47e5-9720-87477702bc6f' User entered '10'	System	04 Aug 2020 19:42:33
	System	04 Aug 2020 19:42:33

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:20', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0b131b0d-6cd5-47e5-9720-87477702bc6f' User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 19:42:33
	System	04 Aug 2020 19:42:33

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0b131b0d-6cd5-47e5-9720-87477702bc6f' User entered '04 Aug 2020 14:42'	System	04 Aug 2020 19:42:33
	System	04 Aug 2020 19:42:33

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 3'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:03', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '45549c17-a913-41cc-89ac-6d3eab63f5cc' User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 19:33:36
	System	05 Aug 2020 19:33:36

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:07', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '45549c17-a913-41cc-89ac-6d3eab63f5cc' User entered 'No (N)'	System	05 Aug 2020 19:33:36
	System	05 Aug 2020 19:33:36

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:12', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '45549c17-a913-41cc-89ac-6d3eab63f5cc' User entered 'Yes (Y)'	System	05 Aug 2020 19:33:36
	System	05 Aug 2020 19:33:36

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:18', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '45549c17-a913-41cc-89ac-6d3eab63f5cc' User entered '55'	System	05 Aug 2020 19:33:36
	System	05 Aug 2020 19:33:36

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:25', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '45549c17-a913-41cc-89ac-6d3eab63f5cc'	System	05 Aug 2020 19:33:36
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 19:33:36

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '45549c17-a913-41cc-89ac-6d3eab63f5cc' User entered '05 Aug 2020 14:33'	System	05 Aug 2020 19:33:36
	System	05 Aug 2020 19:33:36

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 4'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:32', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '66b732c1-6b29-47ca-888f-064fa4bba567'	System	06 Aug 2020 20:08:58
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 20:08:58

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:35', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '66b732c1-6b29-47ca-888f-064fa4bba567' User entered 'No (N)'	System	06 Aug 2020 20:08:58
	System	06 Aug 2020 20:08:58

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:40', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '66b732c1-6b29-47ca-888f-064fa4bba567' User entered 'Yes (Y)'	System	06 Aug 2020 20:08:58
	System	06 Aug 2020 20:08:58

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:45', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '66b732c1-6b29-47ca-888f-064fa4bba567' User entered '4'	System	06 Aug 2020 20:08:58
	System	06 Aug 2020 20:08:58

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:50', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '66b732c1-6b29-47ca-888f-064fa4bba567' User entered 'None (1)'	System	06 Aug 2020 20:08:58
	System	06 Aug 2020 20:08:58

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:53', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '66b732c1-6b29-47ca-888f-064fa4bba567' User entered '06 Aug 2020 15:08'	System	06 Aug 2020 20:08:58
	System	06 Aug 2020 20:08:58

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 5'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:46:48', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1fb6b212-f02e-40a4-831f-bfc5f8765bbc'	System	07 Aug 2020 18:47:10
User entered 'None (1)'	System	07 Aug 2020 18:47:10

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:46:53', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1fb6b212-f02e-40a4-831f-bfc5f8765bbc'	System	07 Aug 2020 18:47:10
User entered 'No (N)'	System	07 Aug 2020 18:47:10

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:46:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1fb6b212-f02e-40a4-831f-bfc5f8765bbc' User entered 'No (N)'	System	07 Aug 2020 18:47:10
	System	07 Aug 2020 18:47:10

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:04', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1fb6b212-f02e-40a4-831f-bfc5f8765bbc'	System	07 Aug 2020 18:47:10
User entered 'None (1)'	System	07 Aug 2020 18:47:10

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:07', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1fb6b212-f02e-40a4-831f-bfc5f8765bbc' User entered '07 Aug 2020 13:47'	System	07 Aug 2020 18:47:10
	System	07 Aug 2020 18:47:10

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 6'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:57:55', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0dbd8535-9961-4ef2-82d9-10e3b7900919' User entered 'None (1)'	System	09 Aug 2020 03:58:24
	System	09 Aug 2020 03:58:24

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:57:58', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0dbd8535-9961-4ef2-82d9-10e3b7900919' User entered 'No (N)'	System	09 Aug 2020 03:58:24
	System	09 Aug 2020 03:58:24

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:58:02', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0dbd8535-9961-4ef2-82d9-10e3b7900919' User entered 'No (N)'	System	09 Aug 2020 03:58:24
	System	09 Aug 2020 03:58:24

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:58:09', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0dbd8535-9961-4ef2-82d9-10e3b7900919' User entered 'None (1)'	System	09 Aug 2020 03:58:24
	System	09 Aug 2020 03:58:24

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:58:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0dbd8535-9961-4ef2-82d9-10e3b7900919' User entered '08 Aug 2020 22:58'	System	09 Aug 2020 03:58:24
	System	09 Aug 2020 03:58:24

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 7'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:30', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c600a387-0a85-4e8e-a51f-9485be5fdaac'	System	09 Aug 2020 21:50:46
User entered 'None (1)'	System	09 Aug 2020 21:50:46

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:33', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c600a387-0a85-4e8e-a51f-9485be5fdaac'	System	09 Aug 2020 21:50:46
User entered 'No (N)'	System	09 Aug 2020 21:50:46

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:36', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c600a387-0a85-4e8e-a51f-9485be5fdaac'	System	09 Aug 2020 21:50:46
User entered 'No (N)'	System	09 Aug 2020 21:50:46

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:43', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c600a387-0a85-4e8e-a51f-9485be5fdaac'	System	09 Aug 2020 21:50:46
User entered 'None (1)'	System	09 Aug 2020 21:50:46

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:45', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c600a387-0a85-4e8e-a51f-9485be5fdaac'	System	09 Aug 2020 21:50:46
User entered '09 Aug 2020 16:50'	System	09 Aug 2020 21:50:46

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 13:05'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 15:35'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:50:48', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2' User entered 'None (0)'	System	03 Aug 2020 21:52:32
	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:50:52', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2' User entered 'None (0)'	System	03 Aug 2020 21:52:32
	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:50:55', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2' User entered 'None (0)'	System	03 Aug 2020 21:52:32
	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:50:58', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2' User entered 'None (0)'	System	03 Aug 2020 21:52:32
	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:51:01', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2' User entered 'None (0)'	System	03 Aug 2020 21:52:32
	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:51:04', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2' User entered 'None (0)'	System	03 Aug 2020 21:52:32
	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:52:21', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2'	System	03 Aug 2020 21:52:32
User entered 'No (N)'	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-03T16:52:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e236cf49-f91b-4093-b6a5-aeb28b687ce2' User entered '03 Aug 2020 16:52'	System	03 Aug 2020 21:52:32
	System	03 Aug 2020 21:52:32

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Aug 2020 16:30'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 2'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered 'None (0)'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered 'None (0)'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:51', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered 'None (0)'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:54', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered 'None (0)'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered 'None (0)'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:42:59', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered 'None (0)'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:43:06', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered 'No (N)'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-04T14:43:09', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '0376cd9d-dc96-4443-b546-2ce051b64e4f' User entered '04 Aug 2020 14:43'	System	04 Aug 2020 19:43:13
	System	04 Aug 2020 19:43:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 3'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered 'None (0)'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:37', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered 'None (0)'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered 'None (0)'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:45', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered 'None (0)'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:48', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered 'None (0)'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:53', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered 'None (0)'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:56', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered 'No (N)'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-05T14:33:59', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '41dd0e30-573e-4e11-94b0-d59c36e6a044' User entered '05 Aug 2020 14:33'	System	05 Aug 2020 19:34:03
	System	05 Aug 2020 19:34:03

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 4'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:08:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered 'None (0)'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:09:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered 'None (0)'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:09:03', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered 'None (0)'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:09:05', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered 'None (0)'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:09:08', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered 'None (0)'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:09:10', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered 'None (0)'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:09:13', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered 'No (N)'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-06T15:09:16', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '472238ca-292e-443b-97e9-e5416f4c3ea1' User entered '06 Aug 2020 15:09'	System	06 Aug 2020 20:09:20
	System	06 Aug 2020 20:09:20

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 5'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:12', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered 'None (0)'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:14', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered 'None (0)'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:16', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered 'None (0)'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:19', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered 'None (0)'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:21', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered 'None (0)'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:23', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered 'None (0)'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:26', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered 'No (N)'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-07T13:47:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '288c16de-b916-4f44-a30d-d62b7279889b' User entered '07 Aug 2020 13:47'	System	07 Aug 2020 18:47:33
	System	07 Aug 2020 18:47:33

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 6'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:58:27', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2' User entered 'None (0)'	System	09 Aug 2020 03:59:22
	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:58:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2' User entered 'None (0)'	System	09 Aug 2020 03:59:22
	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:58:38', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2' User entered 'None (0)'	System	09 Aug 2020 03:59:22
	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:58:55', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2' User entered 'None (0)'	System	09 Aug 2020 03:59:22
	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:59:04', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2' User entered 'None (0)'	System	09 Aug 2020 03:59:22
	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:59:08', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2' User entered 'None (0)'	System	09 Aug 2020 03:59:22
	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:59:15', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2'	System	09 Aug 2020 03:59:22
User entered 'No (N)'	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-08T22:59:19', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bd247803-6539-4b70-9217-9d2475ad4af2'	System	09 Aug 2020 03:59:22
User entered '08 Aug 2020 22:59'	System	09 Aug 2020 03:59:22

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 7'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:51', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered 'None (0)'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:55', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered 'None (0)'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered 'None (0)'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:50:59', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered 'None (0)'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:51:03', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered 'None (0)'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:51:05', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered 'None (0)'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:51:08', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered 'No (N)'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-09T16:51:11', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'c70b67e5-6076-4ab2-9903-4eec9a51797e' User entered '09 Aug 2020 16:51'	System	09 Aug 2020 21:51:13
	System	09 Aug 2020 21:51:13

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 18:07:30

US3812010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 22:35:41

US3812010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '10 Aug 2020'	Breanna Galibert (b) (4)	11 Aug 2020 22:35:41

US3812010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	11 Aug 2020 22:35:41

US3812010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 22:35:41

US3812010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	20 Aug 2020 00:14:49

US3812010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	20 Aug 2020 00:14:49

US3812010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	20 Aug 2020 00:14:58

US3812010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '18 Aug 2020'	Breanna Galibert (b) (4)	20 Aug 2020 00:14:58

US3812010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	20 Aug 2020 00:14:58

US3812010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Breanna Galibert (b) (4)	20 Aug 2020 00:14:58

US3812010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	26 Aug 2020 18:29:01

US3812010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	26 Aug 2020 18:29:01

US3812010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	26 Aug 2020 18:30:12

US3812010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '24 Aug 2020'	Karen Knapp (b) (4)	26 Aug 2020 18:30:12

US3812010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	26 Aug 2020 18:30:12

US3812010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Karen Knapp (b) (4)	26 Aug 2020 18:30:12

US3812010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 14:48:22

US3812010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	28 Aug 2020 14:48:22

US3812010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 14:48:37

US3812010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 08:28:40
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Subject within window' (Site from System).	Anya Penly (b) (4) (b) (4)	04 Sep 2020 22:40:33
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	28 Aug 2020 14:48:37
User entered '28 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	28 Aug 2020 14:48:37

US3812010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	28 Aug 2020 14:48:37

US3812010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'VISIT2'	System	28 Aug 2020 14:48:37

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Aug 2020'	Heather Cherniawski (b) (4)	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '08:06'	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '28 Aug 2020 08:06'	System	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '98.0' F	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Oral (Oral)'	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '68'	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'bpm'	System	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '14'	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'breaths/min'	System	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '122'	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '60'	Heather Cherniawski	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	28 Aug 2020 22:08:57

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Aug 2020'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '09:56'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '28 Aug 2020 09:56'	System	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '98.1' F	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Oral (Oral)'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '68'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'bpm'	System	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '16'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'breaths/min'	System	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '130'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '78'	Heather Cherniawski	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	28 Aug 2020 22:09:44

US3812010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:23

US3812010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Aug 2020'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:23

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Aug 2020'	Breanna Galibert (b) (4)	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '09:21'	Breanna Galibert (b) (4)	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '28 Aug 2020 09:21'	System	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'ONCE'	System	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:50:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 14:49:41

US3812010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:39

US3812010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Aug 2020'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:39

US3812010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '09:14'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:39

US3812010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '28 Aug 2020 09:14'	System	28 Aug 2020 14:51:39

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:50:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Aug 2020'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '09:17'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '28 Aug 2020 09:17'	System	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Breanna Galibert (b) (4)	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Breanna Galibert (b) (4)	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered empty.	System	28 Aug 2020 14:51:52

US3812010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
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	03 Sep 2020 19:25:28
User entered 'Yes (Y)' reason for change: Data Entry Error	System	03 Sep 2020 19:25:28
User opened query 'Data is required. Please complete.' (Site from System).	Karen Knapp (b) (4)	03 Sep 2020 19:25:28
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	03 Sep 2020 19:25:24
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Sep 2020 19:25:24
	(b) (4)	
	Karen Knapp (b) (4)	03 Sep 2020 19:25:10
	(b) (4)	
	Karen Knapp (b) (4)	03 Sep 2020 19:24:59
	(b) (4)	

US3812010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '1'	System	03 Sep 2020 19:25:28
User entered empty.	System	03 Sep 2020 19:25:10
User entered '1'	System	03 Sep 2020 19:24:59

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T09:58:21', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '7e9a95e5-3ce7-4f75-a574-b0bb3500a97a' User entered 'Yes (Y)'	System	28 Aug 2020 14:59:28
	System	28 Aug 2020 14:59:28

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T09:58:36', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '7e9a95e5-3ce7-4f75-a574-b0bb3500a97a' User entered '98.1'	System	28 Aug 2020 14:59:28
	System	28 Aug 2020 14:59:28

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T09:58:48', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '7e9a95e5-3ce7-4f75-a574-b0bb3500a97a' User entered 'No (N)'	System	28 Aug 2020 14:59:28
	System	28 Aug 2020 14:59:28

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T09:59:24', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '7e9a95e5-3ce7-4f75-a574-b0bb3500a97a' User entered '28 Aug 2020 09:59'	System	28 Aug 2020 14:59:28
	System	28 Aug 2020 14:59:28

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 09:41'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:11:06', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1866ea67-1144-404e-b06b-27ba328603cf' User entered 'Yes (Y)'	System	29 Aug 2020 03:11:42
	System	29 Aug 2020 03:11:42

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:11:12', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1866ea67-1144-404e-b06b-27ba328603cf' User entered '98.0'	System	29 Aug 2020 03:11:42
	System	29 Aug 2020 03:11:42

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:11:21', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1866ea67-1144-404e-b06b-27ba328603cf'	System	29 Aug 2020 03:11:42
User entered 'Yes (Y)'	System	29 Aug 2020 03:11:42

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 08:23:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karen Knapp (b) (4)	06 Sep 2020 17:02:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:11:28', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1866ea67-1144-404e-b06b-27ba328603cf'	(b) (4)	
User entered '1'	System	29 Aug 2020 03:11:42
	System	29 Aug 2020 03:11:42
	System	29 Aug 2020 03:11:42

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:11:28', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1866ea67-1144-404e-b06b-27ba328603cf' User entered '0'	System	29 Aug 2020 03:11:42
	System	29 Aug 2020 03:11:42

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:11:39', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1866ea67-1144-404e-b06b-27ba328603cf' User entered '28 Aug 2020 22:11'	System	29 Aug 2020 03:11:42
	System	29 Aug 2020 03:11:42

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 13:06'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 2'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:27:54', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a3253810-47de-42c8-9c8a-fbe64fc3bd29'	System	29 Aug 2020 17:28:38
User entered 'Yes (Y)'	System	29 Aug 2020 17:28:38

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a3253810-47de-42c8-9c8a-fbe64fc3bd29' User entered '100.7'	System	29 Aug 2020 17:28:38
	System	29 Aug 2020 17:28:38

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:05', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a3253810-47de-42c8-9c8a-fbe64fc3bd29'	System	29 Aug 2020 17:28:38
User entered 'Yes (Y)'	System	29 Aug 2020 17:28:38

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 08:23:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Karen Knapp (b) (4)	06 Sep 2020 17:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:13', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a3253810-47de-42c8-9c8a-fbe64fc3bd29'	(b) (4)	
User entered '1'	System	29 Aug 2020 17:28:38
	System	29 Aug 2020 17:28:38
	System	29 Aug 2020 17:28:38

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:13', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a3253810-47de-42c8-9c8a-fbe64fc3bd29' User entered '0'	System	29 Aug 2020 17:28:38
	System	29 Aug 2020 17:28:38

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a3253810-47de-42c8-9c8a-fbe64fc3bd29' User entered '29 Aug 2020 12:28'	System	29 Aug 2020 17:28:38
	System	29 Aug 2020 17:28:38

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 3'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:36:14', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '67071e4c-4386-45b7-8ec2-6824daa5ddba' User entered 'Yes (Y)'	System	30 Aug 2020 18:36:54
	System	30 Aug 2020 18:36:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:36:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '67071e4c-4386-45b7-8ec2-6824daa5ddba' User entered '97.0'	System	30 Aug 2020 18:36:54
	System	30 Aug 2020 18:36:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:36:35', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '67071e4c-4386-45b7-8ec2-6824daa5ddba' User entered 'Yes (Y)'	System	30 Aug 2020 18:36:54
	System	30 Aug 2020 18:36:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 08:23:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karen Knapp (b) (4)	06 Sep 2020 17:03:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:36:44', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '67071e4c-4386-45b7-8ec2-6824daa5ddba'	(b) (4)	
User entered '1'	System	30 Aug 2020 18:36:54
	System	30 Aug 2020 18:36:54
	System	30 Aug 2020 18:36:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:36:44', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '67071e4c-4386-45b7-8ec2-6824daa5ddba' User entered '0'	System	30 Aug 2020 18:36:54
	System	30 Aug 2020 18:36:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:36:51', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '67071e4c-4386-45b7-8ec2-6824daa5ddba' User entered '30 Aug 2020 13:36'	System	30 Aug 2020 18:36:54
	System	30 Aug 2020 18:36:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 4'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:30:32', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f644fd91-a104-45a0-a2d4-6f1a3785b35d' User entered 'Yes (Y)'	System	31 Aug 2020 21:30:54
	System	31 Aug 2020 21:30:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:30:37', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f644fd91-a104-45a0-a2d4-6f1a3785b35d' User entered '98.2'	System	31 Aug 2020 21:30:54
	System	31 Aug 2020 21:30:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:30:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f644fd91-a104-45a0-a2d4-6f1a3785b35d' User entered 'No (N)'	System	31 Aug 2020 21:30:54
	System	31 Aug 2020 21:30:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:30:51', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f644fd91-a104-45a0-a2d4-6f1a3785b35d' User entered '31 Aug 2020 16:30'	System	31 Aug 2020 21:30:54
	System	31 Aug 2020 21:30:54

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 5'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:08', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1d0120eb-a47d-42a1-bfa2-1ae5bdc21cab' User entered 'Yes (Y)'	System	01 Sep 2020 17:15:25
	System	01 Sep 2020 17:15:25

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:14', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1d0120eb-a47d-42a1-bfa2-1ae5bdc21cab' User entered '98.3'	System	01 Sep 2020 17:15:25
	System	01 Sep 2020 17:15:25

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:18', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1d0120eb-a47d-42a1-bfa2-1ae5bdc21cab' User entered 'No (N)'	System	01 Sep 2020 17:15:25
	System	01 Sep 2020 17:15:25

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1d0120eb-a47d-42a1-bfa2-1ae5bdc21cab' User entered '01 Sep 2020 12:15'	System	01 Sep 2020 17:15:25
	System	01 Sep 2020 17:15:25

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 6'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:21:01', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3d76b607-d86f-4d98-a7c9-61242ec4e819' User entered 'Yes (Y)'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:21:21', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3d76b607-d86f-4d98-a7c9-61242ec4e819' User entered '98.2'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:21:38', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3d76b607-d86f-4d98-a7c9-61242ec4e819' User entered 'No (N)'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:21:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3d76b607-d86f-4d98-a7c9-61242ec4e819' User entered '03 Sep 2020 10:21'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 7'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a461b054-86f2-40a2-b6c0-2dfa0c38758a' User entered 'Yes (Y)'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:35', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a461b054-86f2-40a2-b6c0-2dfa0c38758a' User entered '97.3'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:38', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a461b054-86f2-40a2-b6c0-2dfa0c38758a' User entered 'No (N)'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:42', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a461b054-86f2-40a2-b6c0-2dfa0c38758a' User entered '03 Sep 2020 15:05'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:00:14', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'aba756f8-f109-4e72-8542-55bcd730c448'	System	28 Aug 2020 15:01:27
User entered 'None (1)'	System	28 Aug 2020 15:01:27

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:11', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'aba756f8-f109-4e72-8542-55bcd730c448' User entered 'No (N)'	System	28 Aug 2020 15:01:27
	System	28 Aug 2020 15:01:27

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:15', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'aba756f8-f109-4e72-8542-55bcd730c448' User entered 'No (N)'	System	28 Aug 2020 15:01:27
	System	28 Aug 2020 15:01:27

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:19', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'aba756f8-f109-4e72-8542-55bcd730c448' User entered 'None (1)'	System	28 Aug 2020 15:01:27
	System	28 Aug 2020 15:01:27

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:23', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'aba756f8-f109-4e72-8542-55bcd730c448' User entered '28 Aug 2020 10:01'	System	28 Aug 2020 15:01:27
	System	28 Aug 2020 15:01:27

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 09:41'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:02', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a5c7e833-0357-4be4-8e9a-bb8c6d910b1f' User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 03:12:26
	System	29 Aug 2020 03:12:26

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:05', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a5c7e833-0357-4be4-8e9a-bb8c6d910b1f' User entered 'No (N)'	System	29 Aug 2020 03:12:26
	System	29 Aug 2020 03:12:26

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:08', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a5c7e833-0357-4be4-8e9a-bb8c6d910b1f' User entered 'Yes (Y)'	System	29 Aug 2020 03:12:26
	System	29 Aug 2020 03:12:26

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:13', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a5c7e833-0357-4be4-8e9a-bb8c6d910b1f' User entered '6'	System	29 Aug 2020 03:12:26
	System	29 Aug 2020 03:12:26

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:18', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a5c7e833-0357-4be4-8e9a-bb8c6d910b1f' User entered 'None (1)'	System	29 Aug 2020 03:12:26
	System	29 Aug 2020 03:12:26

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a5c7e833-0357-4be4-8e9a-bb8c6d910b1f' User entered '28 Aug 2020 22:12'	System	29 Aug 2020 03:12:26
	System	29 Aug 2020 03:12:26

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 13:06'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 2'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:42', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '26808efa-c8e4-44c4-9343-bed3323fd0aa'	System	29 Aug 2020 17:30:00
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 17:30:00

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '26808efa-c8e4-44c4-9343-bed3323fd0aa' User entered 'No (N)'	System	29 Aug 2020 17:30:00
	System	29 Aug 2020 17:30:00

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:28:50', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '26808efa-c8e4-44c4-9343-bed3323fd0aa' User entered 'Yes (Y)'	System	29 Aug 2020 17:30:00
	System	29 Aug 2020 17:30:00

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:29:33', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '26808efa-c8e4-44c4-9343-bed3323fd0aa' User entered '6'	System	29 Aug 2020 17:30:00
	System	29 Aug 2020 17:30:00

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:29:54', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '26808efa-c8e4-44c4-9343-bed3323fd0aa' User entered 'None (1)'	System	29 Aug 2020 17:30:00
	System	29 Aug 2020 17:30:00

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:29:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '26808efa-c8e4-44c4-9343-bed3323fd0aa' User entered '29 Aug 2020 12:29'	System	29 Aug 2020 17:30:00
	System	29 Aug 2020 17:30:00

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 3'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:37:01', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'cf31c766-e182-4747-8050-d8998c3981ed'	System	30 Aug 2020 18:38:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	30 Aug 2020 18:38:51

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:37:07', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'cf31c766-e182-4747-8050-d8998c3981ed' User entered 'Yes (Y)'	System	30 Aug 2020 18:38:51
	System	30 Aug 2020 18:38:51

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:38:10', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'cf31c766-e182-4747-8050-d8998c3981ed' User entered '10'	System	30 Aug 2020 18:38:51
	System	30 Aug 2020 18:38:51

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:38:16', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'cf31c766-e182-4747-8050-d8998c3981ed' User entered 'Yes (Y)'	System	30 Aug 2020 18:38:51
	System	30 Aug 2020 18:38:51

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:38:30', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'cf31c766-e182-4747-8050-d8998c3981ed' User entered '10'	System	30 Aug 2020 18:38:51
	System	30 Aug 2020 18:38:51

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:38:43', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'cf31c766-e182-4747-8050-d8998c3981ed'	System	30 Aug 2020 18:38:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	30 Aug 2020 18:38:51

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:38:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'cf31c766-e182-4747-8050-d8998c3981ed' User entered '30 Aug 2020 13:38'	System	30 Aug 2020 18:38:51
	System	30 Aug 2020 18:38:51

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 4'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:02', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '425a51f5-56df-47d7-8ea4-605261e168be' User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 21:31:46
	System	31 Aug 2020 21:31:46

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:06', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '425a51f5-56df-47d7-8ea4-605261e168be' User entered 'No (N)'	System	31 Aug 2020 21:31:46
	System	31 Aug 2020 21:31:46

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:10', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '425a51f5-56df-47d7-8ea4-605261e168be' User entered 'Yes (Y)'	System	31 Aug 2020 21:31:46
	System	31 Aug 2020 21:31:46

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:19', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '425a51f5-56df-47d7-8ea4-605261e168be' User entered '6'	System	31 Aug 2020 21:31:46
	System	31 Aug 2020 21:31:46

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:38', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '425a51f5-56df-47d7-8ea4-605261e168be' User entered 'None (1)'	System	31 Aug 2020 21:31:46
	System	31 Aug 2020 21:31:46

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '425a51f5-56df-47d7-8ea4-605261e168be' User entered '31 Aug 2020 16:31'	System	31 Aug 2020 21:31:46
	System	31 Aug 2020 21:31:46

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 5'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:26', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '50c70dd1-1581-4dc1-b82c-6242dbac140c' User entered 'None (1)'	System	01 Sep 2020 17:16:04
	System	01 Sep 2020 17:16:04

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '50c70dd1-1581-4dc1-b82c-6242dbac140c' User entered 'No (N)'	System	01 Sep 2020 17:16:04
	System	01 Sep 2020 17:16:04

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '50c70dd1-1581-4dc1-b82c-6242dbac140c' User entered 'Yes (Y)'	System	01 Sep 2020 17:16:04
	System	01 Sep 2020 17:16:04

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:52', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '50c70dd1-1581-4dc1-b82c-6242dbac140c' User entered '4'	System	01 Sep 2020 17:16:04
	System	01 Sep 2020 17:16:04

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:15:56', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '50c70dd1-1581-4dc1-b82c-6242dbac140c' User entered 'None (1)'	System	01 Sep 2020 17:16:04
	System	01 Sep 2020 17:16:04

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '50c70dd1-1581-4dc1-b82c-6242dbac140c' User entered '01 Sep 2020 12:16'	System	01 Sep 2020 17:16:04
	System	01 Sep 2020 17:16:04

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 6'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:21:53', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71f6b6a0-ed42-4267-8322-2f2b039ea872' User entered 'None (1)'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:21:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71f6b6a0-ed42-4267-8322-2f2b039ea872' User entered 'No (N)'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:06', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71f6b6a0-ed42-4267-8322-2f2b039ea872' User entered 'Yes (Y)'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:16', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71f6b6a0-ed42-4267-8322-2f2b039ea872' User entered '2'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:21', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71f6b6a0-ed42-4267-8322-2f2b039ea872'	System	25 Sep 2020 15:04:55
User entered 'None (1)'	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:23', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71f6b6a0-ed42-4267-8322-2f2b039ea872' User entered '03 Sep 2020 10:22'	System	25 Sep 2020 15:04:55
	System	25 Sep 2020 15:04:55

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 7'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:49', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '76922dd1-0f31-4249-be58-46ca5306017e' User entered 'None (1)'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:53', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '76922dd1-0f31-4249-be58-46ca5306017e' User entered 'No (N)'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:56', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '76922dd1-0f31-4249-be58-46ca5306017e' User entered 'No (N)'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:05:58', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '76922dd1-0f31-4249-be58-46ca5306017e' User entered 'None (1)'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '76922dd1-0f31-4249-be58-46ca5306017e' User entered '03 Sep 2020 15:06'	System	25 Sep 2020 15:04:57
	System	25 Sep 2020 15:04:57

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:28', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered 'None (0)'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered 'None (0)'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:36', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered 'None (0)'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:39', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered 'None (0)'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:43', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered 'None (0)'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered 'None (0)'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:52', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered 'No (N)'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T10:01:56', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '32a0df6d-87c8-4b73-b252-48dec4096b25' User entered '28 Aug 2020 10:01'	System	28 Aug 2020 15:02:00
	System	28 Aug 2020 15:02:00

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 09:41'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 12:11'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:27', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered 'None (0)'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:30', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered 'None (0)'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered 'None (0)'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:39', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered 'None (0)'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered 'None (0)'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:44', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered 'None (0)'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:51', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered 'No (N)'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-28T22:12:55', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '33e7d3ba-c826-4eed-91d7-ee5243e7a1e8' User entered '28 Aug 2020 22:12'	System	29 Aug 2020 03:12:58
	System	29 Aug 2020 03:12:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '28 Aug 2020 13:06'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 2'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:30:17', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571'	System	29 Aug 2020 17:31:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:30:23', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571'	System	29 Aug 2020 17:31:16
User entered 'Some interference with activity (2)'	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:30:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571'	System	29 Aug 2020 17:31:16
User entered 'Some interference with activity (2)'	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:30:42', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571'	System	29 Aug 2020 17:31:16
User entered 'Significant; prevents daily activity (3)'	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:30:50', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571' User entered 'None (0)'	System	29 Aug 2020 17:31:16
	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:31:02', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571'	System	29 Aug 2020 17:31:16
User entered 'Some interference with activity not requiring medical attention (2)'	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:31:06', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571' User entered 'No (N)'	System	29 Aug 2020 17:31:16
	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-29T12:31:11', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'f1842258-dde7-4860-98b8-fc0558049571' User entered '29 Aug 2020 12:31'	System	29 Aug 2020 17:31:16
	System	29 Aug 2020 17:31:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 3'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:38:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020' User entered 'None (0)'	System	30 Aug 2020 18:39:46
	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:39:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020' User entered 'None (0)'	System	30 Aug 2020 18:39:46
	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:39:08', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020' User entered 'None (0)'	System	30 Aug 2020 18:39:46
	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:39:17', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020'	System	30 Aug 2020 18:39:46
User entered 'No interference with activity (1)'	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:39:20', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020' User entered 'None (0)'	System	30 Aug 2020 18:39:46
	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:39:32', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020'	System	30 Aug 2020 18:39:46
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:39:38', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020' User entered 'No (N)'	System	30 Aug 2020 18:39:46
	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-30T13:39:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '71609b64-eb1b-4020-b692-ad5cf89b1020' User entered '30 Aug 2020 13:39'	System	30 Aug 2020 18:39:46
	System	30 Aug 2020 18:39:46

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 4'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:46', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered 'None (0)'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:48', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered 'None (0)'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:52', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered 'None (0)'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:55', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered 'None (0)'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:31:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered 'None (0)'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:32:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered 'None (0)'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:32:04', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered 'No (N)'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-08-31T16:32:10', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3cb77ef2-ac95-4d67-87f9-04c3bb1e0a39' User entered '31 Aug 2020 16:32'	System	31 Aug 2020 21:32:16
	System	31 Aug 2020 21:32:16

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 5'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:04', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered 'None (0)'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:07', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered 'None (0)'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:09', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered 'None (0)'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:12', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered 'None (0)'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:15', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered 'None (0)'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:17', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered 'None (0)'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:23', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered 'No (N)'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-01T12:16:25', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b36d2d46-1f39-4eb0-9c2b-c3a7a70ecc39' User entered '01 Sep 2020 12:16'	System	01 Sep 2020 17:16:27
	System	01 Sep 2020 17:16:27

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 6'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered 'None (0)'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered 'None (0)'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered 'None (0)'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:37', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered 'None (0)'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered 'None (0)'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:43', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered 'None (0)'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:46', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered 'No (N)'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T10:22:49', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'bcd10090-a94d-41bf-aae9-1118c7e3039d' User entered '03 Sep 2020 10:22'	System	25 Sep 2020 15:04:56
	System	25 Sep 2020 15:04:56

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	28 Aug 2020 14:49:41
User entered 'Day 7'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:04', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered 'None (0)'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:07', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered 'None (0)'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:09', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered 'None (0)'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:11', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered 'None (0)'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:13', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered 'None (0)'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:15', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered 'None (0)'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:19', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered 'No (N)'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-09-03T15:06:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '54a1a7da-9f8b-421e-aa68-0e6648361df8' User entered '03 Sep 2020 15:06'	System	25 Sep 2020 15:04:58
	System	25 Sep 2020 15:04:58

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:49:41

US3812010

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:50:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:49:41

US3812010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:06:54

US3812010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	10 Nov 2020 18:51:16
User entered '6 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 03:06:54

US3812010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:06:54

US3812010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:06:54

US3812010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	12 Sep 2020 16:09:56

US3812010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	12 Sep 2020 16:09:56

US3812010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	12 Sep 2020 16:10:16

US3812010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '12 Sep 2020'	Karen Knapp (b) (4)	12 Sep 2020 16:10:16

US3812010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	12 Sep 2020 16:10:16

US3812010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Karen Knapp (b) (4)	12 Sep 2020 16:10:16

US3812010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	12 Sep 2020 16:10:24

US3812010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	12 Sep 2020 16:10:24

US3812010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 19:54:46

US3812010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '18 Sep 2020'	Karen Knapp (b) (4)	18 Sep 2020 19:54:46

US3812010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	18 Sep 2020 19:54:46

US3812010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Karen Knapp (b) (4)	18 Sep 2020 19:54:46

US3812010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 19:54:51

US3812010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	18 Sep 2020 19:54:51

US3812010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Oct 2020 20:52:32

US3812010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	19 Oct 2020 20:52:32

US3812010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	19 Oct 2020 20:52:32

US3812010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'VISIT3'	System	19 Oct 2020 20:52:32

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '09:25'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '28 Sep 2020 09:25'	System	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '97.4' F	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '63'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'bpm'	System	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '16'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'breaths/min'	System	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '128'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '70'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'mmHg'	System	19 Oct 2020 20:53:00

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26

US3812010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26

US3812010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'No (N)'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:10

US3812010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 20:53:10

US3812010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:19

US3812010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '28 Sep 2020'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:19

US3812010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '09:40'	Breanna Galibert (b) (4)	19 Oct 2020 20:53:19

US3812010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered '28 Sep 2020 09:40'	System	19 Oct 2020 20:53:19

US3812010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Oct 2020 14:30:28

US3812010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	18 Oct 2020 14:30:28

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 64'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-03T05:13:18', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a9f4bc9c-238d-4c12-98a8-ccdfc5132893'	System	03 Oct 2020 10:13:38
User entered 'No (N)'	System	03 Oct 2020 10:13:38

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-03T05:13:25', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a9f4bc9c-238d-4c12-98a8-ccdfc5132893'	System	03 Oct 2020 10:13:38
User entered 'No (N)'	System	03 Oct 2020 10:13:38

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-03T05:13:35', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a9f4bc9c-238d-4c12-98a8-ccdfe5132893' User entered '03 Oct 2020 05:13:35'	System	03 Oct 2020 10:13:38
	System	03 Oct 2020 10:13:38

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 71'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-11T14:25:39', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '9b9da198-076f-4119-ae0b-cc8c27ca2cf5'	System	11 Oct 2020 19:25:56
User entered 'No (N)'	System	11 Oct 2020 19:25:56

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-11T14:25:43', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '9b9da198-076f-4119-ae0b-cc8c27ca2cf5'	System	11 Oct 2020 19:25:56
User entered 'No (N)'	System	11 Oct 2020 19:25:56

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-11T14:25:51', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '9b9da198-076f-4119-ae0b-cc8c27ca2cf5' User entered '11 Oct 2020 14:25:51'	System	11 Oct 2020 19:25:56
	System	11 Oct 2020 19:25:56

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 78'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-17T06:17:45', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e01746d7-f4e1-4ca6-bfcd-c0551006779b' User entered 'No (N)'	System	17 Oct 2020 11:18:01
	System	17 Oct 2020 11:18:01

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-17T06:17:54', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e01746d7-f4e1-4ca6-bfcd-c0551006779b'	System	17 Oct 2020 11:18:01
User entered 'No (N)'	System	17 Oct 2020 11:18:01

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-17T06:17:59', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e01746d7-f4e1-4ca6-bfcd-c0551006779b' User entered '17 Oct 2020 06:17:59'	System	17 Oct 2020 11:18:01
	System	17 Oct 2020 11:18:01

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 92'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-31T08:56:15', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '062f8cd0-b326-4f37-bae7-fa6892201900' User entered 'No (N)'	System	31 Oct 2020 13:56:32
	System	31 Oct 2020 13:56:32

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-31T08:56:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '062f8cd0-b326-4f37-bae7-fa6892201900'	System	31 Oct 2020 13:56:32
User entered 'No (N)'	System	31 Oct 2020 13:56:32

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-10-31T08:56:28', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '062f8cd0-b326-4f37-bae7-fa6892201900' User entered '31 Oct 2020 08:56:28'	System	31 Oct 2020 13:56:32
	System	31 Oct 2020 13:56:32

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 99'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-09T12:33:16', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '49d10b64-086f-41fa-91d6-5a8bb052560d' User entered 'Yes (Y)'	System	09 Nov 2020 18:34:07
	System	09 Nov 2020 18:34:07

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-09T12:33:22', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '49d10b64-086f-41fa-91d6-5a8bb052560d' User entered 'Yes (Y)'	System	09 Nov 2020 18:34:07
	System	09 Nov 2020 18:34:07

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-09T12:33:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '49d10b64-086f-41fa-91d6-5a8bb052560d'	System	09 Nov 2020 18:34:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 18:34:07

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-09T12:33:37', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '49d10b64-086f-41fa-91d6-5a8bb052560d' User entered 'No (N)'	System	09 Nov 2020 18:34:07
	System	09 Nov 2020 18:34:07

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-09T12:33:43', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '49d10b64-086f-41fa-91d6-5a8bb052560d' User entered 'No (N)'	System	09 Nov 2020 18:34:07
	System	09 Nov 2020 18:34:07

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-09T12:33:58', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '49d10b64-086f-41fa-91d6-5a8bb052560d' User entered '09 Nov 2020 12:33:58'	System	09 Nov 2020 18:34:07
	System	09 Nov 2020 18:34:07

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered 'Day 106'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-14T00:01:25', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '4a3a526a-dd25-4031-958c-4fa2d655a83f' User entered 'No (N)'	System	14 Nov 2020 06:02:00
	System	14 Nov 2020 06:02:00

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-14T00:01:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '4a3a526a-dd25-4031-958c-4fa2d655a83f' User entered 'Yes (Y)'	System	14 Nov 2020 06:02:00
	System	14 Nov 2020 06:02:00

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-14T00:01:42', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '4a3a526a-dd25-4031-958c-4fa2d655a83f' User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 06:02:00

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-14T00:01:48', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '4a3a526a-dd25-4031-958c-4fa2d655a83f' User entered '14 Nov 2020 00:01:48'	System	14 Nov 2020 06:02:00
	System	14 Nov 2020 06:02:00

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 18:07:30

US3812010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:20:44
Data entry locked.	System	03 Aug 2020 18:07:30
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 18:07:30

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-21T11:15:18', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '738a23f7-2966-4887-a34b-cf95865bf1c6'	System	21 Nov 2020 17:15:33
User entered 'No (N)'	System	21 Nov 2020 17:15:33

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-21T11:15:24', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '738a23f7-2966-4887-a34b-cf95865bf1c6'	System	21 Nov 2020 17:15:33
User entered 'No (N)'	System	21 Nov 2020 17:15:33

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-21T11:15:27', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '738a23f7-2966-4887-a34b-cf95865bf1c6' User entered '21 Nov 2020 11:15:27'	System	21 Nov 2020 17:15:33
	System	21 Nov 2020 17:15:33

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-26T09:04:25', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5b1ca6b5-e2fc-4457-b85f-d66b7f7e0fb4' User entered 'No (N)'	System	26 Nov 2020 15:04:36
	System	26 Nov 2020 15:04:36

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-26T09:04:29', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5b1ca6b5-e2fc-4457-b85f-d66b7f7e0fb4' User entered 'No (N)'	System	26 Nov 2020 15:04:36
	System	26 Nov 2020 15:04:36

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-11-26T09:04:33', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5b1ca6b5-e2fc-4457-b85f-d66b7f7e0fb4' User entered '26 Nov 2020 09:04:33'	System	26 Nov 2020 15:04:36
	System	26 Nov 2020 15:04:36

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-04T08:54:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1085c1f4-ae60-4bff-9873-db4243934ba2'	System	04 Dec 2020 14:55:13
User entered 'Yes (Y)'	System	04 Dec 2020 14:55:13

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-04T08:54:38', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1085c1f4-ae60-4bff-9873-db4243934ba2'	System	04 Dec 2020 14:55:13
User entered 'No (N)'	System	04 Dec 2020 14:55:13

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-04T08:54:42', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1085c1f4-ae60-4bff-9873-db4243934ba2'	System	04 Dec 2020 14:55:13
User entered 'No (N)'	System	04 Dec 2020 14:55:13

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-04T08:54:50', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1085c1f4-ae60-4bff-9873-db4243934ba2' User entered 'Yes (Y)'	System	04 Dec 2020 14:55:13
	System	04 Dec 2020 14:55:13

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Please 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-04T08:54:58', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1085c1f4-ae60-4bff-9873-db4243934ba2'	System	04 Dec 2020 14:55:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 14:55:13

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-04T08:55:02', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1085c1f4-ae60-4bff-9873-db4243934ba2' User entered '04 Dec 2020 08:55:02'	System	04 Dec 2020 14:55:13
	System	04 Dec 2020 14:55:13

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-09T07:48:52', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '704ebbeb-262a-4146-a5a5-983f2a1bbddd' User entered 'No (N)'	System	09 Dec 2020 13:49:05
	System	09 Dec 2020 13:49:05

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-09T07:48:58', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '704ebbeb-262a-4146-a5a5-983f2a1bbddd'	System	09 Dec 2020 13:49:05
User entered 'No (N)'	System	09 Dec 2020 13:49:05

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-09T07:49:02', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '704ebbeb-262a-4146-a5a5-983f2a1bbddd' User entered '09 Dec 2020 07:49:02'	System	09 Dec 2020 13:49:05
	System	09 Dec 2020 13:49:05

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-18T08:21:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1d8eac9a-9ad2-41fb-b286-9ababe8fdc4b'	System	18 Dec 2020 14:21:40
User entered 'No (N)'	System	18 Dec 2020 14:21:40

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-18T08:21:35', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1d8eac9a-9ad2-41fb-b286-9ababe8fdc4b'	System	18 Dec 2020 14:21:40
User entered 'No (N)'	System	18 Dec 2020 14:21:40

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-18T08:21:38', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1d8eac9a-9ad2-41fb-b286-9ababe8fdc4b' User entered '18 Dec 2020 08:21:38'	System	18 Dec 2020 14:21:40
	System	18 Dec 2020 14:21:40

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-23T00:01:40', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8cd860f0-4756-427c-a1c3-ab5e52745a0a' User entered 'No (N)'	System	23 Dec 2020 06:04:06
	System	23 Dec 2020 06:04:06

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-23T00:03:54', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8cd860f0-4756-427c-a1c3-ab5e52745a0a' User entered 'No (N)'	System	23 Dec 2020 06:04:06
	System	23 Dec 2020 06:04:06

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-23T00:04:01', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8cd860f0-4756-427c-a1c3-ab5e52745a0a' User entered '23 Dec 2020 00:04:01'	System	23 Dec 2020 06:04:06
	System	23 Dec 2020 06:04:06

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-30T08:53:26', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b17ecb27-b1fb-4e20-9959-8326f53024a4' User entered 'Yes (Y)'	System	30 Dec 2020 14:54:23
	System	30 Dec 2020 14:54:23

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-30T08:53:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b17ecb27-b1fb-4e20-9959-8326f53024a4' User entered 'No (N)'	System	30 Dec 2020 14:54:23
	System	30 Dec 2020 14:54:23

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-30T08:53:39', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b17ecb27-b1fb-4e20-9959-8326f53024a4' User entered 'No (N)'	System	30 Dec 2020 14:54:23
	System	30 Dec 2020 14:54:23

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-30T08:53:45', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b17ecb27-b1fb-4e20-9959-8326f53024a4'	System	30 Dec 2020 14:54:23
User entered 'Yes (Y)'	System	30 Dec 2020 14:54:23

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Please 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-30T08:54:06', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b17ecb27-b1fb-4e20-9959-8326f53024a4'	System	30 Dec 2020 14:54:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 14:54:23

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2020-12-30T08:54:11', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'b17ecb27-b1fb-4e20-9959-8326f53024a4' User entered '30 Dec 2020 08:54:11'	System	30 Dec 2020 14:54:23
	System	30 Dec 2020 14:54:23

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-08T12:01:16', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3911a1aa-2ff8-4ee0-a48a-bed3c5042df3' User entered 'Yes (Y)'	System	08 Jan 2021 18:02:01
	System	08 Jan 2021 18:02:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-08T12:01:25', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3911a1aa-2ff8-4ee0-a48a-bed3c5042df3'	System	08 Jan 2021 18:02:01
User entered 'No (N)'	System	08 Jan 2021 18:02:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-08T12:01:30', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3911a1aa-2ff8-4ee0-a48a-bed3c5042df3' User entered 'No (N)'	System	08 Jan 2021 18:02:01
	System	08 Jan 2021 18:02:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-08T12:01:36', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3911a1aa-2ff8-4ee0-a48a-bed3c5042df3' User entered 'Yes (Y)'	System	08 Jan 2021 18:02:01
	System	08 Jan 2021 18:02:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Please 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-08T12:01:41', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3911a1aa-2ff8-4ee0-a48a-bed3c5042df3'	System	08 Jan 2021 18:02:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 18:02:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-08T12:01:50', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3911a1aa-2ff8-4ee0-a48a-bed3c5042df3' User entered '08 Jan 2021 12:01:50'	System	08 Jan 2021 18:02:01
	System	08 Jan 2021 18:02:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-13T07:24:54', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '46b8ca88-5f74-4189-bcf4-38cf52b77fdf' User entered 'No (N)'	System	13 Jan 2021 13:25:06
	System	13 Jan 2021 13:25:06

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-13T07:24:57', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '46b8ca88-5f74-4189-bcf4-38cf52b77fdf' User entered 'No (N)'	System	13 Jan 2021 13:25:06

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-13T07:25:03', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '46b8ca88-5f74-4189-bcf4-38cf52b77fdf' User entered '13 Jan 2021 07:25:03'	System	13 Jan 2021 13:25:06
	System	13 Jan 2021 13:25:06

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-20T08:19:46', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1f3d5c74-107b-4330-9eda-f5a544d2a201' User entered 'No (N)'	System	20 Jan 2021 14:19:56
	System	20 Jan 2021 14:19:56

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-20T08:19:50', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1f3d5c74-107b-4330-9eda-f5a544d2a201' User entered 'No (N)'	System	20 Jan 2021 14:19:56
	System	20 Jan 2021 14:19:56

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-20T08:19:53', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1f3d5c74-107b-4330-9eda-f5a544d2a201' User entered '20 Jan 2021 08:19:53'	System	20 Jan 2021 14:19:56
	System	20 Jan 2021 14:19:56

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-28T15:35:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3d21df0b-64a3-44f8-8148-1db45785627c' User entered 'No (N)'	System	28 Jan 2021 21:35:44
	System	28 Jan 2021 21:35:44

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-28T15:35:36', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3d21df0b-64a3-44f8-8148-1db45785627c' User entered 'No (N)'	System	28 Jan 2021 21:35:44
	System	28 Jan 2021 21:35:44

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-01-28T15:35:40', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3d21df0b-64a3-44f8-8148-1db45785627c' User entered '28 Jan 2021 15:35:40'	System	28 Jan 2021 21:35:44
	System	28 Jan 2021 21:35:44

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-04T11:12:31', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'be104694-4e1b-4a90-99b2-098dc282f711' User entered 'No (N)'	System	04 Feb 2021 17:14:01
	System	04 Feb 2021 17:14:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-04T11:12:34', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'be104694-4e1b-4a90-99b2-098dc282f711' User entered 'No (N)'	System	04 Feb 2021 17:14:01
	System	04 Feb 2021 17:14:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-04T11:12:47', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'be104694-4e1b-4a90-99b2-098dc282f711' User entered '04 Feb 2021 11:12:47'	System	04 Feb 2021 17:14:01
	System	04 Feb 2021 17:14:01

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-11T18:19:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e42d7396-fea6-41e4-a546-b6018a186143' User entered 'No (N)'	System	12 Feb 2021 00:22:15
	System	12 Feb 2021 00:22:15

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-11T18:19:05', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e42d7396-fea6-41e4-a546-b6018a186143' User entered 'No (N)'	System	12 Feb 2021 00:22:15
	System	12 Feb 2021 00:22:15

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-11T18:19:08', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'e42d7396-fea6-41e4-a546-b6018a186143' User entered '11 Feb 2021 18:19:08'	System	12 Feb 2021 00:22:15
	System	12 Feb 2021 00:22:15

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-17T05:22:01', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '77b5310f-5afb-4f21-9f1a-8b8b6e5a5741' User entered 'No (N)'	System	17 Feb 2021 11:22:14
	System	17 Feb 2021 11:22:14

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-17T05:22:06', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '77b5310f-5afb-4f21-9f1a-8b8b6e5a5741' User entered 'No (N)'	System	17 Feb 2021 11:22:14

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-17T05:22:11', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '77b5310f-5afb-4f21-9f1a-8b8b6e5a5741' User entered '17 Feb 2021 05:22:11'	System	17 Feb 2021 11:22:14
	System	17 Feb 2021 11:22:14

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-26T14:26:09-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5f3c3409-96d1-422e-988e-dd7e475e57ae' User entered 'No (N)'	System	26 Feb 2021 20:26:24
	System	26 Feb 2021 20:26:24

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-26T14:26:03-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5f3c3409-96d1-422e-988e-dd7e475e57ae'	System	26 Feb 2021 20:26:24
User entered 'No (N)'	System	26 Feb 2021 20:26:24

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-02-26T14:26:21-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '5f3c3409-96d1-422e-988e-dd7e475e57ae' User entered '26 Feb 2021 20:26:21'	System	26 Feb 2021 20:26:24
	System	26 Feb 2021 20:26:24

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-06T09:38:31-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ce638256-2111-4262-9724-de88fb4ada6a'	System	06 Mar 2021 15:38:44
User entered 'No (N)'	System	06 Mar 2021 15:38:44

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-06T09:38:34-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ce638256-2111-4262-9724-de88fb4ada6a'	System	06 Mar 2021 15:38:44
User entered 'No (N)'	System	06 Mar 2021 15:38:44

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-06T09:38:38-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'ce638256-2111-4262-9724-de88fb4ada6a' User entered '06 Mar 2021 09:38:38'	System	06 Mar 2021 15:38:44
	System	06 Mar 2021 15:38:44

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-10T08:26:15-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '6c393b98-b03d-4657-b1aa-f629cfdbbb29'	System	10 Mar 2021 14:26:37
User entered 'No (N)'	System	10 Mar 2021 14:26:37

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-10T08:26:25-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '6c393b98-b03d-4657-b1aa-f629cfdbbb29'	System	10 Mar 2021 14:26:37
User entered 'No (N)'	System	10 Mar 2021 14:26:37

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-10T08:26:30-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '6c393b98-b03d-4657-b1aa-f629cfdbbb29'	System	10 Mar 2021 14:26:37
User entered '10 Mar 2021 08:26:30'	System	10 Mar 2021 14:26:37

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-17T15:41:16-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '2ea1073f-6fa3-457d-8e28-cb4a80c3d8cc'	System	17 Mar 2021 20:41:33
User entered 'No (N)'	System	17 Mar 2021 20:41:33

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-17T15:41:23-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '2ea1073f-6fa3-457d-8e28-cb4a80c3d8cc'	System	17 Mar 2021 20:41:33
User entered 'No (N)'	System	17 Mar 2021 20:41:33

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-17T15:41:26-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '2ea1073f-6fa3-457d-8e28-cb4a80c3d8cc'	System	17 Mar 2021 20:41:33
User entered '17 Mar 2021 15:41:26'	System	17 Mar 2021 20:41:33

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-26T08:12:26-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3dabbe1e-17bf-42fc-9395-4ba8dc8b0d26'	System	26 Mar 2021 13:12:39
User entered 'No (N)'	System	26 Mar 2021 13:12:39

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-26T08:12:29-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3dabbe1e-17bf-42fc-9395-4ba8dc8b0d26'	System	26 Mar 2021 13:12:39
User entered 'No (N)'	System	26 Mar 2021 13:12:39

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-26T08:12:32-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '3dabbe1e-17bf-42fc-9395-4ba8dc8b0d26' User entered '26 Mar 2021 08:12:32'	System	26 Mar 2021 13:12:39
	System	26 Mar 2021 13:12:39

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-04-03T10:06:23-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '93f58bf8-7043-452b-862d-6589e2f444da'	System	03 Apr 2021 15:06:34
User entered 'No (N)'	System	03 Apr 2021 15:06:34

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-04-03T10:06:26-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '93f58bf8-7043-452b-862d-6589e2f444da'	System	03 Apr 2021 15:06:34
User entered 'No (N)'	System	03 Apr 2021 15:06:34

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-04-03T10:06:30-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '93f58bf8-7043-452b-862d-6589e2f444da' User entered '03 Apr 2021 10:06:30'	System	03 Apr 2021 15:06:34
	System	03 Apr 2021 15:06:34

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (FF52E801-0C27-46A5-9FCC-E7FC3AFCA96F)', Time: '2021-04-10T09:34:55-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1c6f2103-b5fb-4d4d-a72b-963ccd8e67e2'	System	10 Apr 2021 14:35:05
User entered 'No (N)'	System	10 Apr 2021 14:35:05

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (FF52E801-0C27-46A5-9FCC-E7FC3AFCA96F)', Time: '2021-04-10T09:34:59-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1c6f2103-b5fb-4d4d-a72b-963ccd8e67e2'	System	10 Apr 2021 14:35:05
User entered 'No (N)'	System	10 Apr 2021 14:35:05

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF52E801-0C27-46A5-9FCC-E7FC3AFCA96F)', Time: '2021-04-10T09:35:02-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '1c6f2103-b5fb-4d4d-a72b-963ccd8e67e2'	System	10 Apr 2021 14:35:05
User entered '10 Apr 2021 09:35:02'	System	10 Apr 2021 14:35:05

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (FF52E801-0C27-46A5-9FCC-E7FC3AFCA96F)', Time: '2021-04-14T07:01:38-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a654b8bb-0d39-45fb-8c79-6c6653644ffa' User entered 'No (N)'	System	14 Apr 2021 14:29:18
	System	14 Apr 2021 14:29:18

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (FF52E801-0C27-46A5-9FCC-E7FC3AFCA96F)', Time: '2021-04-14T07:01:44-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a654b8bb-0d39-45fb-8c79-6c6653644ffa'	System	14 Apr 2021 14:29:18
User entered 'No (N)'	System	14 Apr 2021 14:29:18

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FF52E801-0C27-46A5-9FCC-E7FC3AFCA96F)', Time: '2021-04-14T07:01:58-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'a654b8bb-0d39-45fb-8c79-6c6653644ffa'	System	14 Apr 2021 14:29:18
User entered '14 Apr 2021 07:01:58'	System	14 Apr 2021 14:29:18

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-22T14:33:08-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8d34ee8c-6f16-4aae-b7a7-e28aecaf7226'	System	22 Apr 2021 19:33:59
User entered 'Yes (Y)'	System	22 Apr 2021 19:33:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Have you been exposed to someone with 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 (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-22T14:33:18-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8d34ee8c-6f16-4aae-b7a7-e28aeca7226'	System	22 Apr 2021 19:33:59
User entered 'No (N)'	System	22 Apr 2021 19:33:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-22T14:33:23-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8d34ee8c-6f16-4aae-b7a7-e28aeca7226'	System	22 Apr 2021 19:33:59
User entered 'No (N)'	System	22 Apr 2021 19:33:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-22T14:33:33-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8d34ee8c-6f16-4aae-b7a7-e28aecaf7226'	System	22 Apr 2021 19:33:59
User entered 'Yes (Y)'	System	22 Apr 2021 19:33:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Please 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 (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-22T14:33:40-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8d34ee8c-6f16-4aae-b7a7-e28aecaf7226'	System	22 Apr 2021 19:33:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Apr 2021 19:33:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-22T14:33:47-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '8d34ee8c-6f16-4aae-b7a7-e28aeca7226'	System	22 Apr 2021 19:33:59
User entered '22 Apr 2021 14:33:47'	System	22 Apr 2021 19:33:59

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[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 (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-28T04:48:15-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '511e7942-60ae-4b1c-86f3-09065d835d41' User entered 'No (N)'	System	29 Apr 2021 02:42:48
	System	29 Apr 2021 02:42:48

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

Have you been exposed to someone with 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 (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-28T04:48:20-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '511e7942-60ae-4b1c-86f3-09065d835d41'	System	29 Apr 2021 02:42:48
User entered 'No (N)'	System	29 Apr 2021 02:42:48

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86444233-43BB-4A0E-B1AE-9461DC250190)', Time: '2021-04-28T04:48:23-05:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: '511e7942-60ae-4b1c-86f3-09065d835d41'	System	29 Apr 2021 02:42:48
User entered '28 Apr 2021 04:48:23'	System	29 Apr 2021 02:42:48

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:51:46

US3812010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:50:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:51:46
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:51:46

US3812010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:50:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:22:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-06T09:38:46-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'd8babb5d-ea5d-475f-a9f8-ed84244c318b' User entered 'No (N)'	System	06 Mar 2021 15:38:56
	System	06 Mar 2021 15:38:56

US3812010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:50:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:22:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2CEB1260-0E57-426B-B8EF-3D2116A364E6)', Time: '2021-03-06T09:38:53-06:00', User OID: 'PatientReportedOutcome (US3812010)', ODM File OID: 'd8babb5d-ea5d-475f-a9f8-ed84244c318b' User entered '06 Mar 2021 09:38:53'	System	06 Mar 2021 15:38:56
	System	06 Mar 2021 15:38:56

US3812010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Oct 2020 14:06:47

US3812010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '23 Oct 2020'	Karen Knapp (b) (4)	23 Oct 2020 14:06:47

US3812010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	23 Oct 2020 14:06:47

US3812010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Karen Knapp (b) (4)	23 Oct 2020 14:06:47

US3812010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Oct 2020 14:06:51

US3812010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:20:26
User entered 'I'	System	23 Oct 2020 14:06:51

US3812010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Karen Knapp (b) (4)	24 Nov 2020 15:13:55

US3812010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '24 Nov 2020'	Karen Knapp (b) (4)	24 Nov 2020 15:13:55

US3812010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	24 Nov 2020 15:13:55

US3812010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Karen Knapp (b) (4)	24 Nov 2020 15:13:55

US3812010

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Karen Knapp (b) (4)	24 Nov 2020 15:14:01

US3812010

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'I'	System	24 Nov 2020 15:14:01

US3812010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Dec 2020 15:01:22

US3812010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '23 Dec 2020'	Karen Knapp (b) (4)	23 Dec 2020 15:01:22

US3812010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	23 Dec 2020 15:01:22

US3812010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Karen Knapp (b) (4)	23 Dec 2020 15:01:22

US3812010

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Dec 2020 15:01:27

US3812010

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'I'	System	23 Dec 2020 15:01:27

US3812010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Jan 2021 19:12:11

US3812010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered '23 Jan 2021'	Karen Knapp (b) (4)	23 Jan 2021 19:12:11

US3812010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	23 Jan 2021 19:12:11

US3812010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered empty.	Karen Knapp (b) (4)	23 Jan 2021 19:12:11

US3812010

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Jan 2021 19:12:16

US3812010

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'I'	System	23 Jan 2021 19:12:16

US3812010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Mar 2021 22:16:40

US3812010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '01 Mar 2021'	Breanna Galibert (b) (4)	01 Mar 2021 22:16:40

US3812010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	01 Mar 2021 22:16:40

US3812010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'VISIT4'	System	01 Mar 2021 22:16:40

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered 'Yes (Y)'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered '01 Mar 2021'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered '09:00'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered '01 Mar 2021 09:00'	System	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered '97.0' F	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered 'Oral (Oral)'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered '67'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'bpm'	System	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered '13'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'breaths/min'	System	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
User entered '118'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'mmHg'	System	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 14:21:41
User signature succeeded.	Lyly Dang (b) (4)	02 Apr 2021 18:47:21
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per investigator' (Site from System).	Lyly Dang (b) (4)	02 Apr 2021 18:47:11
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Apr 2021 18:46:25
User entered '58'	Lyly Dang (b) (4)	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'mmHg'	System	02 Apr 2021 18:46:25

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07

US3812010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07

US3812010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Mar 2021 22:17:02

US3812010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '01 Mar 2021'	Breanna Galibert (b) (4)	01 Mar 2021 22:17:02

US3812010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Mar 2021 22:17:07

US3812010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '01 Mar 2021'	Breanna Galibert (b) (4)	01 Mar 2021 22:17:07

US3812010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '09:25'	Breanna Galibert (b) (4)	01 Mar 2021 22:17:07

US3812010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered '01 Mar 2021 09:25'	System	01 Mar 2021 22:17:07

US3812010

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Mar 2021 22:17:17

US3812010

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:32:07
User entered 'I'	System	01 Mar 2021 22:17:17

US3812010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	24 Mar 2021 18:12:10

US3812010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	24 Mar 2021 18:12:18
User entered '24 Mar 2021' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	24 Mar 2021 18:12:18
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	24 Mar 2021 18:12:10
User entered '25 Mar 2021'	Maureen Dempsey (b) (4)	24 Mar 2021 18:12:10

US3812010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Contact Made (CONTACT MADE)'	Maureen Dempsey (b) (4)	24 Mar 2021 18:12:10

US3812010

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Maureen Dempsey (b) (4)	24 Mar 2021 18:12:10

US3812010

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	24 Mar 2021 18:12:22

US3812010

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User entered 'I'	System	24 Mar 2021 18:12:22

US3812010

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'visit has not occurred yet' (Site from System).	Angie Kean (b) (4)	03 May 2021 21:15:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	03 May 2021 21:11:15
User entered 'Yes (Y)'	Angie Kean (b) (4)	03 May 2021 21:11:15
	(b) (4)	
	Breanna Galibert (b) (4)	03 May 2021 17:23:11
	(b) (4)	

US3812010

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 May 2021 21:11:15
Query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	03 May 2021 21:11:15
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	03 May 2021 21:11:15
User entered '03 May 2021' reason for change: Data Entry Error	Angie Kean (b) (4)	03 May 2021 21:10:44
User opened query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 May 2021 17:23:11
User entered '29 Apr 2021'	Breanna Galibert (b) (4)	03 May 2021 17:23:11

US3812010

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	03 May 2021 21:11:15
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:11

US3812010

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:50:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:11

US3812010

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	03 May 2021 19:23:59
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 17:23:16

US3812010

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:50:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:23:16

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:50:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:30
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 09:43:59
Query 'Data is required. Please complete.' answered with 'please inactivate' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 15:24:23
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 15:24:16
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:28:09
User entered '14 Aug 2020'	Karen Knapp (b) (4)	21 Aug 2020 19:17:18

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:50:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:30
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 09:44:00
Query 'Data is required. Please complete.' answered with 'please inactivate' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 15:24:29
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 15:24:16
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:28:09
User entered '14:15'	Karen Knapp (b) (4)	21 Aug 2020 19:17:18

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:50:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:30
User entered empty.	System	21 Apr 2021 15:24:16
User entered '14 Aug 2020 14:15'	System	21 Aug 2020 19:17:18

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:50:16

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:30
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 09:44:02
Query 'Data is required. Please complete.' answered with 'please inactivate ' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 15:24:35
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 15:24:16
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:28:09
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Karen Knapp (b) (4)	21 Aug 2020 19:17:18

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:50:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:30
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 09:44:04
Query 'Data is required. Please complete.' answered with 'please inactivate' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 15:24:42
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 15:24:16
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 15:24:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:28:09
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 21:09:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 21:09:23
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4)	24 Aug 2020 21:09:23
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:17:18
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:17:18

US3812010

Folder: Covid-19 Assessment 14 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:50:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:43:36
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:34:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 09:43:49
Query 'Data is required. Please complete.' answered with 'please inactivate' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 15:24:53
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 15:24:46
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:46
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 15:24:46
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 15:24:46
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:28:29
User entered 'No (N)'	Heather Cherniawski (b) (4)	26 Oct 2020 16:31:40

US3812010

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:10

US3812010

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '18 Jan 2021'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:10

US3812010

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:10

US3812010

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

Form: Visit Date

Generated On: 10 Jun 2021 09:50:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 19:58:10

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '18 Jan 2021'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:26

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 15:59:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:13:58

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:26

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4)	09 Mar 2021 15:59:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:13:58

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '18 Jan 2021'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:26

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mRNA-1273 (mRNA-1273)'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:26

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:14:51
User entered 'mRNA-1273 (mRNA-1273)'	Heather Cherniawski	18 Jan 2021 19:58:26
	(b) (4)	

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:14:51
User entered 'mRNA-1273 (mRNA-1273)'	Heather Cherniawski	18 Jan 2021 19:58:26
	(b) (4)	

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:26

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User entered empty.	System	18 Jan 2021 19:58:26

US3812010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:50:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User entered empty.	System	18 Jan 2021 19:58:26

US3812010

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:56

US3812010

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '18 Jan 2021'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:56

US3812010

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '12:40'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:56

US3812010

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User entered '18 Jan 2021 12:40'	System	18 Jan 2021 19:58:56

US3812010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:43

US3812010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '18 Jan 2021'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:43

US3812010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '12:45'	Heather Cherniawski (b) (4)	18 Jan 2021 19:58:43

US3812010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:33:36
User entered '18 Jan 2021 12:45'	System	18 Jan 2021 19:58:43

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:50:16

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
User closed query 'Please move information from this UNS to a illness visit page. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:34:44
Query 'Please move information from this UNS to a illness visit page. Thank you.' answered with 'This was an unscheduled visit, not illness. Please advise' (Site from CRA).	Angie Kean (b) (4) (b) (4)	20 Nov 2020 17:45:09
User opened query 'Please move information from this UNS to a illness visit page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:11:26
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:19
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 21:25:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 21:25:52
User entered '14 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:25:52
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 15:09:24
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:24
User entered '14 Aug 2020'	(b) (4), (b) (6)	18 Sep 2020 02:55:41

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:50:16

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:19
User entered '1' reason for change: Data Entry Error	Breanna Galibert (b) (4)	11 Nov 2020 21:25:52
User entered '0' reason for change: Data Entry Error	(b) (4) Breanna Galibert (b) (4)	04 Nov 2020 15:09:24
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 02:55:41

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:50:16

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:19
User entered '1' reason for change: Data Entry Error	Breanna Galibert (b) (4)	11 Nov 2020 21:25:52
User entered '0' reason for change: Data Entry Error	(b) (4) Breanna Galibert (b) (4)	04 Nov 2020 15:09:24
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 02:55:41

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:50:16

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:19
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 02:55:41

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:50:16

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:19
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 02:55:41

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 21:26:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 21:26:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:30
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 15:09:45
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered '14 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Data Entry Error	(b) (4) Breanna Galibert (b) (4)	04 Nov 2020 15:09:45
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered '14:20' reason for change: Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:45
User closed query 'Per CDM: Response noted, please update the required field 'Time of assessment' . Else clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:10:21
Query 'Per CDM: Response noted, please update the required field 'Time of assessment' . Else clarify. ' answered with 'updated per source' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:46:23
User entered '14:20' reason for change: Per Query Resolution	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:46:09
User opened query 'Per CDM: Response noted, please update the required field 'Time of assessment' . Else clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:06:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 05:41:36
Query 'Data is required. Please provide.' answered with 'NOT DONE' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 02:57:31
User opened query 'Data is required. Please provide.' System (Site from System).		18 Sep 2020 02:57:08
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User entered '14 Aug 2020 14:20'	System	11 Nov 2020 21:26:30
User entered empty.	System	04 Nov 2020 15:09:45
User entered '14 Aug 2020 14:20'	System	14 Oct 2020 19:46:09
User entered empty.	System	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered '97.6' F reason for change: Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:45
User closed query 'Per CDM: Response noted, hence please update ND in the Temperature field.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:10:29
Query 'Per CDM: Response noted, hence please update ND in the Temperature field.' answered with 'updated per source' (Site from DM).	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:46:54
User entered '97.6' F reason for change: Per Query Resolution	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:46:37
User opened query 'Per CDM: Response noted, hence please update ND in the Temperature field.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:00:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 05:41:38
Query 'Data is required. Please provide.' answered with 'NOT DONE' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 02:57:33
User opened query 'Data is required. Please provide.' System (Site from System).		18 Sep 2020 02:57:08
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered 'Oral (Oral)' reason for change: Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:45
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 19:47:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		14 Oct 2020 19:47:05
User entered 'Oral (Oral)' reason for change: Per Query Resolution	Maureen Dempsey (b) (4) (b) (4)	14 Oct 2020 19:47:05
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 19:46:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered '71' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:45
User entered '71'	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User entered 'bpm'	System	11 Nov 2020 21:26:30
User entered empty.	System	04 Nov 2020 15:09:45
User entered 'bpm'	System	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered '14' reason for change: Data Entry Error	Breanna Galibert (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	04 Nov 2020 15:09:45
User entered '14'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User entered 'breaths/min'	System	11 Nov 2020 21:26:30
User entered empty.	System	04 Nov 2020 15:09:45
User entered 'breaths/min'	System	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered '132' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:45
User entered '132'	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User entered 'mmHg'	System	11 Nov 2020 21:26:30
User entered empty.	System	04 Nov 2020 15:09:45
User entered 'mmHg'	System	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:29:45
User entered '72' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:30
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:45
User entered '72'	(b) (4), (b) (6)	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43
User entered 'mmHg'	System	11 Nov 2020 21:26:30
User entered empty.	System	04 Nov 2020 15:09:45
User entered 'mmHg'	System	18 Sep 2020 02:57:08

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	24 Apr 2021 18:47:43

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Vital Signs

Generated On: 10 Jun 2021 09:50:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:43

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:47
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:30:20
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 21:26:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 21:26:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:42
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 15:09:54
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 02:58:09

US3812010

Folder: Unscheduled 14 Aug 2020

Form: Physical Examination

Generated On: 10 Jun 2021 09:50:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:47:47
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:30:20
User entered '14 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	11 Nov 2020 21:26:42
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:09:54
User entered '14 Aug 2020'	(b) (4), (b) (6)	18 Sep 2020 02:58:09

US3812010

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:50:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:56
User closed query 'Per DM CLR: Per Day 124 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:19:14
Query 'Per DM CLR: Per Day 124 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'updated. AE added' (Site from DM).	Angie Kean (b) (4) (b) (4)	30 Mar 2021 16:42:48
User opened query 'Per DM CLR: Per Day 124 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:36:44
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:27
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	15 Aug 2020 18:13:17

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:03:42
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash maculo-papular, LLT: Localized maculopapular rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:30:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:30:34
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Lyly Dang (b) (4)	11 Nov 2020 19:29:15
Data point term sent to Coder	System	11 Nov 2020 19:27:14
User entered 'NON-URTICARIAL MACULOPAPULAR RASH TO LEFT UPPER ARM (BELOW INJECTION SITE)' reason for change: Data Entry Error	Lyly Dang (b) (4)	11 Nov 2020 19:27:03
User opened query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:38:37
User closed query 'Per CDM re-query: Site response is noted; however, please update the Adverse event field with 'Maculopapular' as the type of rash. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:38:31
Data point term sent to Coder	System	02 Nov 2020 18:09:37

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Site response is noted; however, please update the Adverse event field with 'Maculopapular' as the type of rash. Thank you.' answered with 'updated per query' (Site from DM). Coding entries removed.	Anya Penly (b) (4) (b) (4)	02 Nov 2020 18:08:57
User entered 'maculopapular RASH TO LEFT UPPER ARM (BELOW INJECTION SITE)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	02 Nov 2020 18:08:47
User opened query 'Per CDM re-query: Site response is noted; however, please update the Adverse event field with 'Maculopapular' as the type of rash. Thank you.' (Site from DM).	Anya Penly (b) (4) (b) (4)	02 Nov 2020 18:08:47
User closed query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Papular, Maculopapular, Pustular, etc.). Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:32:14
Query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Papular, Maculopapular, Pustular, etc.). Please update as appropriate or provide clarification. ' answered with 'MACULOPAPULAR' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Oct 2020 00:02:07
User opened query 'Per DM CLR: Please review AE and please update to specify the type of Rash (e.g. Papular, Maculopapular, Pustular, etc.). Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Sep 2020 15:36:24
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site rash, LLT: Injection site rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:10:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:10:42
Data point term sent to Coder	System	21 Aug 2020 19:11:32
User entered 'RASH TO LEFT UPPER ARM (BELOW INJECTION SITE)'	Karen Knapp (b) (4) (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 21:07:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 21:07:45
User entered 'No (N)' reason for change: Data Entry Error	Any Penly (b) (4)	24 Aug 2020 21:07:45
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:11:10
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 21:07:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 21:07:45
User entered 'No (N)' reason for change: Data Entry Error	Any Penly (b) (4)	24 Aug 2020 21:07:45
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:11:10
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 17:51:32
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	28 Aug 2020 14:49:41
User entered '12 Aug 2020'	Karen Knapp (b) (4) (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
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).	System	24 Aug 2020 21:08:00
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4)	24 Aug 2020 21:08:00
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	21 Aug 2020 19:11:10
User entered '07:00'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User entered empty.	System	24 Aug 2020 21:08:00
User entered '12 Aug 2020 07:00'	System	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '14 Aug 2020'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Aug 2020 21:08:13
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4)	24 Aug 2020 21:08:13
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Aug 2020 19:11:10
User entered '10:00'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User entered empty.	System	24 Aug 2020 21:08:13
User entered '14 Aug 2020 10:00'	System	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Related (RELATED)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'I'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User entered '0'	System	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42
User entered 'I'	System	21 Aug 2020 19:11:10

US3812010

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:42

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:14:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:14:15
Data point term sent to Coder	System	21 Aug 2020 19:13:40
User entered 'NECK PAIN'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not listed as one of the solicited events and the start date of this AE was after the period of SAR assessment. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:28:19
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not listed as one of the solicited events and the start date of this AE was after the period of SAR assessment. Please review and update accordingly. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	20 Oct 2020 13:13:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 13:13:23
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not listed as one of the solicited events and the start date of this AE was after the period of SAR assessment. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 15:37:02
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 21:08:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 21:08:49
User entered 'No (N)' reason for change: Data Entry Error	Any Penly (b) (4)	24 Aug 2020 21:08:49
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 19:13:28
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 17:51:37
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	28 Aug 2020 14:49:41
User entered '12 Aug 2020'	Karen Knapp (b) (4) (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
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).	System	24 Aug 2020 21:08:49
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4)	24 Aug 2020 21:08:49
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	21 Aug 2020 19:13:28
User entered '07:00'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User entered empty.	System	24 Aug 2020 21:08:49
User entered '12 Aug 2020 07:00'	System	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '14 Aug 2020'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Aug 2020 21:08:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 21:08:49
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4)	24 Aug 2020 21:08:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 19:13:28
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	21 Aug 2020 19:13:28
User entered 'UN:UN' (non-conformant).	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User entered empty.	System	24 Aug 2020 21:08:49
User entered '14 Aug 2020 UN:UN' (non-conformant).	System	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'l'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Karen Knapp (b) (4)	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User entered '0'	System	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46
User entered 'I'	System	21 Aug 2020 19:13:28

US3812010

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:46

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:31:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:26:08
User entered	System	30 Dec 2020 16:18:23
'USA-US111-2020-mRNA-1273-P301000024'		
User entered 'New'	(b) (4), (b) (6)	30 Dec 2020 16:18:23

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:31:54
User closed query 'PV Query: Please consider updating the event term to the final diagnosis (etiology of the chest tightness), if known. If you remain as chest tightness, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 21:23:46
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina unstable, LLT: Unstable angina - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 19:24:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 19:24:57
	(b) (4)	
Query 'PV Query: Please consider updating the event term to the final diagnosis (etiology of the chest tightness), if known. If you remain as chest tightness, please state so.' answered with 'updated' (Site from Safety).	Angie Kean (b) (4)	25 Jan 2021 19:23:53
	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 19:23:51
Coding entries removed.	Angie Kean (b) (4)	25 Jan 2021 19:23:33
	(b) (4)	
User entered 'unstable angina' reason for change: New Information	Angie Kean (b) (4)	25 Jan 2021 19:23:33
	(b) (4)	
User opened query 'PV Query: Please consider updating the event term to the final diagnosis (etiology of the chest tightness), if known. If you remain as chest tightness, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:12:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 01:35:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 01:35:24
	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 01:34:15
User entered 'CHEST TIGHTNESS'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	09 Mar 2021 20:32:04
User entered 'Yes (Y)'	Angie Kean (b) (4)- (b) (4)	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:05
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:18
User entered '23 Dec 2020'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:21
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:27
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:29
User entered '04 Jan 2021' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 15:04:24
User entered '28 Dec 2020'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:31
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Narrative states this event was an SAE due to medical significance. Event serious criteria is reported as caused/prolonged hospitalization. Please reconcile event seriousness criteria.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:38:45
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
Query 'PV Query: Narrative states this event was an SAE due to medical significance. Event serious criteria is reported as caused/prolonged hospitalization. Please reconcile event seriousness criteria.' answered with 'confirmed serious criteria is due to requires inpatient hospitalization' (Site from Safety).	Anya Penly (b) (4)	07 Apr 2021 16:55:45
User opened query 'PV Query: Narrative states this event was an SAE due to medical significance. Event serious criteria is reported as caused/prolonged hospitalization. Please reconcile event seriousness criteria.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 13:49:19
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:35
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:39
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:40
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:32:42
	(b) (4), (b) (6)	
User closed query 'PV Query: Please update seriousness criteria for the event based on the source document, considering that the patient was not hospitalized for the event unstable angina.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 16:09:51
Query 'PV Query: Please update seriousness criteria for the event based on the source document, considering that the patient was not hospitalized for the event unstable angina.' answered with 'data is correct. subject was hospitalized for this event. ' (Site from Safety).	Angie Kean (b) (4) (b) (4)	24 Feb 2021 18:42:41
User opened query 'PV Query: Please update seriousness criteria for the event based on the source document, considering that the patient was not hospitalized for the event unstable angina.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 16:15:33
User entered 'I'	Angie Kean (b) (4) (b) (4)	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:35:39
User closed query 'PV Query: Please confirm whether the subject was hospitalized from 26Dec2020 - 28Dec2020 as noted in the source document. If hospitalized please provide details, and if not hospitalized please update report. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 16:09:55
Query 'PV Query: Please confirm whether the subject Angie Kean was hospitalized from 26Dec2020 - 28Dec2020 as noted in the source document. If hospitalized please provide details, and if not hospitalized please update report. ' answered with 'data is correct' (Site from Safety).	Angie Kean (b) (4) (b) (4)	24 Feb 2021 18:43:10
User opened query 'PV Query: Please confirm whether the subject was hospitalized from 26Dec2020 - 28Dec2020 as noted in the source document. If hospitalized please provide details, and if not hospitalized please update report. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 16:15:52
User entered '26 Dec 2020'	Angie Kean (b) (4) (b) (4)	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming that subject was not admitted into the hospital. Please update hospital admission and discharge dates in narrative.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	08 Apr 2021 14:38:53
	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
Query 'PV Query: Thank you for confirming that subject was not admitted into the hospital. Please update hospital admission and discharge dates in narrative.' answered with 'Changed narrative note to reflect confirmed dates. Subject hospitalized 26 DEC 2020 TO 28 DEC 2021. Subject had outpatient cath on 04JAN21, which reflects stop date in AE. ' (Site from Safety).	lauren clement (b) (4)	07 Apr 2021 17:14:09
User opened query 'PV Query: Thank you for confirming that subject was not admitted into the hospital. Please update hospital admission and discharge dates in narrative.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 13:49:48
	(b) (4), (b) (6)	09 Mar 2021 20:42:11
User entered '28 Dec 2020'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:39:36
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:39:38
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:39:39
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:00
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:01
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:03
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:05
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:07
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:11
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:12
User entered 'I'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:14
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 15:04:24
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:40:17
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:33:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:45:11
DataPoint Un-verified.	lauren clement (b) (4) [REDACTED] [REDACTED]	07 Apr 2021 17:12:53

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User entered "THE SUBJECT IS A 71-YEAR-OLD MALE WITH A HISTORY OF TYPE TWO DIABETES, HYPERTENSION, HYPERLIPIDEMIA, GASTROESOPHAGEAL REFLUX DISEASE, AND OBSTRUCTIVE SLEEP APNEA WHO PRESENTED TO THE EMERGENCY DEPARTMENT ON 26 DECEMBER 2020 WITH A THREE DAY HISTORY OF EXERTIONAL SHORTNESS OF BREATH AND CHEST TIGHTNESS. HE PRESENTED TO THE EMERGENCY DEPARTMENT WHEN HE BEGAN TO EXPERIENCE SHORTNESS OF BREATH AND CHEST TIGHTNESS AT REST. CHEST X-RAY WAS UNREMARKABLE. ECG SHOWED RIGHT BUNDLE BRANCH BLOCK CONSISTENT WITH A PRIOR ECG. RESTING ECHOCARDIOGRAPHY WAS UNREMARKABLE. STRESS ECHOCARDIOGRAM WAS POSITIVE FOR MYOCARDIAL ISCHEMIA IN THE MID-LEFT ANTERIOR DESCENDING ARTERY DISTRIBUTION ACCOMPANIED BY ANGINAL CHEST PAIN AND A HYPERTENSIVE RESPONSE TO EXERCISE. HE WAS DISCHARGED ON 28DEC2020 FROM HOSPITAL. ON 04JAN21 SUBJECT REPORTED TO OUTPATIENT CARDIAC CATHETERIZATION LAB, AND UNDERWENT RIGHT AND LEFT CORONARY ANGIOGRAPHY, INTRAVASCULAR ULTRASOUND OF THE LEFT ANTERIOR DESCENDING ARTERY, AND PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT PLACED INTO THE LEFT ANTERIOR DESCENDING CORONARY ARTERY. HE WAS FOUND TO HAVE A 99% MID-LEFT ANTERIOR DESCENDING ARTERY LESION AND A 70% PROXIMAL LEFT ANTERIOR DESCENDING CORONARY ARTERY LESION. BOTH LESIONS WERE STENTED. HE WAS STARTED ON	lauren clement (b) (4)	07 Apr 2021 17:12:53

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
CLOPIDOGREL 75 MG DAILY AND CONTINUED THERAPY WITH ONE BABY ASPIRIN DAILY. TROPONINS STAYED WITHIN THE NORMAL RANGE. BRAIN NATRIURETIC PEPTIDE WAS NORMAL (5 PG/ML, REF <OR = 300). THIS IS BEEN REPORTED AS A SERIOUS ADVERSE EVENT DUE TO BEING AN IMPORTANT MEDICAL EVENT AND, GIVEN THE SEVERITY OF HIS CORONARY ARTERY LESIONS, WOULD LIKELY HAVE BEEN FATAL WITHOUT INTERVENTION.'		
reason for change: Per Query Resolution User closed query 'PV Query: Please confirm the date the subject was taken to the catheterization lab and underwent right and left coronary angiography, intravascular ultrasound of the left anterior descending artery, and percutaneous intervention with a drug eluting stent placed into the left anterior descending coronary artery as it was noted the subject was not admitted to the hospital and was treated as an outpatient, but hospitalization admission date of 26Dec2020 and discharge 28Dec2020 are provided in narrative. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 14:53:17
	(b) (4), (b) (6)	16 Mar 2021 14:35:24
User closed query 'Per DM RQ: Narrative indicates that subject had "CHEST X-RAY, ECG, RESTING ECHOCARDIOGRAPHY, STRESS ECHOCARDIOGRAM, CARDIAC CATHETERIZATION, & PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 13:38:26
	lauren clement (b) (4)	15 Mar 2021 21:05:08

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT IS A 71-YEAR-OLD MALE WITH A HISTORY OF TYPE TWO DIABETES, HYPERTENSION, HYPERLIPIDEMIA, GASTROESOPHAGEAL REFLUX DISEASE, AND OBSTRUCTIVE SLEEP APNEA WHO PRESENTED TO THE EMERGENCY DEPARTMENT ON 26 DECEMBER 2020 WITH A THREE DAY HISTORY OF EXERTIONAL SHORTNESS OF BREATH AND CHEST TIGHTNESS. HE PRESENTED TO THE EMERGENCY DEPARTMENT WHEN HE BEGAN TO EXPERIENCE SHORTNESS OF BREATH AND CHEST TIGHTNESS AT REST. CHEST X-RAY WAS UNREMARKABLE. ECG SHOWED RIGHT BUNDLE BRANCH BLOCK CONSISTENT WITH A PRIOR ECG. RESTING ECHOCARDIOGRAPHY WAS UNREMARKABLE. STRESS ECHOCARDIOGRAM WAS POSITIVE FOR MYOCARDIAL ISCHEMIA IN THE MID-LEFT ANTERIOR DESCENDING ARTERY DISTRIBUTION ACCOMPANIED BY ANGINAL CHEST PAIN AND A HYPERTENSIVE RESPONSE TO EXERCISE. IN OUTPATIENT CARDIAC CATHETERIZATION LAB ON 04JAN2021, THIS SUBJECT UNDERWENT RIGHT AND LEFT CORONARY ANGIOGRAPHY, INTRAVASCULAR ULTRASOUND OF THE LEFT ANTERIOR DESCENDING ARTERY, AND PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT PLACED INTO THE LEFT ANTERIOR DESCENDING CORONARY ARTERY. HE WAS FOUND TO HAVE A 99% MID-LEFT ANTERIOR DESCENDING ARTERY LESION AND A 70% PROXIMAL LEFT ANTERIOR DESCENDING CORONARY ARTERY LESION. BOTH LESIONS WERE STENTED. HE WAS STARTED ON CLOPIDOGREL 75 MG DAILY AND CONTINUED THERAPY WITH ONE BABY	lauren clement (b) (4)	15 Mar 2021 21:05:08

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
ASPIRIN DAILY. TROPONINS STAYED WITHIN THE NORMAL RANGE. BRAIN NATRIURETIC PEPTIDE WAS NORMAL (5 PG/ML, REF <OR = 300). THE SUBJECT STATED THAT HE WAS NOT ADMITTED TO THE HOSPITAL AND THAT THIS WAS TREATED AS AN OUTPATIENT. HIS RECORDS SUPPORT THIS. THIS IS BEEN REPORTED AS A SERIOUS ADVERSE EVENT DUE TO BEING AN IMPORTANT MEDICAL EVENT AND, GIVEN THE SEVERITY OF HIS CORONARY ARTERY LESIONS, WOULD LIKELY HAVE BEEN FATAL WITHOUT INTERVENTION.' reason for change: New Information Query 'PV Query: Please confirm the date the subject lauren clement (b) (4) was taken to the catheterization lab and underwent right and left coronary angiography, intravascular ultrasound of the left anterior descending artery, and percutaneous intervention with a drug eluting stent placed into the left anterior descending coronary artery as it was noted the subject was not admitted to the hospital and was treated as an outpatient, but hospitalization admission date of 26Dec2020 and discharge 28Dec2020 are provided in narrative. ' answered with 'Correct; as reflected in concomitant procedures; these were done outpatient on 04JAN2021' (Site from Safety). Query 'Per DM RQ: Narrative indicates that subject lauren clement (b) (4) had "CHEST X-RAY, ECG, RESTING ECHOCARDIOGRAPHY, STRESS ECHOCARDIOGRAM, CARDIAC CATHETERIZATION, & PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'right and left coronary angiography are missing from concomitant procedures, will add that now. This is specific to the cardiac catheterization.' (Site from DM).		
	lauren clement (b) (4)	15 Mar 2021 21:00:57
	lauren clement (b) (4)	15 Mar 2021 20:57:41

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm the date the subject was taken to the catheterization lab and underwent right and left coronary angiography, intravascular ultrasound of the left anterior descending artery, and percutaneous intervention with a drug eluting stent placed into the left anterior descending coronary artery as it was noted the subject was not admitted to the hospital and was treated as an outpatient, but hospitalization admission date of 26Dec2020 and discharge 28Dec2020 are provided in narrative. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:05:44
	(b) (4), (b) (6)	09 Mar 2021 20:40:19
User closed query 'PV Query: Please confirm the date the subject was taken to the catheterization lab and underwent right and left coronary angiography, intravascular ultrasound of the left anterior descending artery, and percutaneous intervention with a drug eluting stent placed into the left anterior descending coronary artery as it was noted the subject was not admitted to the hospital and was treated as an outpatient' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 17:26:01
User closed query 'PV Query: Please provide medical records related to serious event of unstable angina. ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 17:25:57
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 17:25:54
User opened query 'Per DM RQ: Narrative indicates that subject had "CHEST X-RAY, ECG, RESTING ECHOCARDIOGRAPHY, STRESS ECHOCARDIOGRAM, CARDIAC CATHETERIZATION, & PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:43:52

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "CHEST X-RAY, ECG, RESTING ECHOCARDIOGRAPHY, STRESS ECHOCARDIOGRAM, CARDIAC CATHETERIZATION, & PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:43:31
Query 'Per DM CLR: Narrative indicates that subject had "CHEST X-RAY, ECG, RESTING ECHOCARDIOGRAPHY, STRESS ECHOCARDIOGRAM, CARDIAC CATHETERIZATION, & PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'NO problem will add these now.' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 15:03:26
Query 'PV Query: Please confirm the date the subject was taken to the catheterization lab and underwent right and left coronary angiography, intravascular ultrasound of the left anterior descending artery, and percutaneous intervention with a drug eluting stent placed into the left anterior descending coronary artery as it was noted the subject was not admitted to the hospital and was treated as an outpatient' answered with 'The subject went on 04JAN2021; redacted copies have been sent to you on 04MAR2021' (Site from Safety).	lauren clement (b) (4)	08 Mar 2021 15:02:48
Query 'PV Query: Please provide medical records related to serious event of unstable angina. ' answered with 'This was completed on 04MAR2021' (Site from Safety).	lauren clement (b) (4)	08 Mar 2021 15:01:48

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'This was completed on 04MAR2021' (Site from Safety).	lauren clement (b) (4)	08 Mar 2021 15:01:28
User opened query 'Per DM CLR: Narrative indicates that subject had "CHEST X-RAY, ECG, RESTING ECHOCARDIOGRAPHY, STRESS ECHOCARDIOGRAM, CARDIAC CATHETERIZATION, & PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT." However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:14:42
User opened query 'PV Query: Please confirm the date the subject was taken to the catheterization lab and underwent right and left coronary angiography, intravascular ultrasound of the left anterior descending artery, and percutaneous intervention with a drug eluting stent placed into the left anterior descending coronary artery as it was noted the subject was not admitted to the hospital and was treated as an outpatient' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 16:16:38
User opened query 'PV Query: Please provide medical records related to serious event of unstable angina. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 16:16:09
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 16:14:37
User closed query 'Per DM CLR: SAE Narrative = NORMAL EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:35:39

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = NORMAL EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Per several previous queries, only therapeutic procedures are to be recorded. EKG is not a therapeutic procedure. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	28 Jan 2021 14:18:07

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'The subject is a 71-year-old male with a history of type two diabetes, hypertension, hyperlipidemia, gastroesophageal reflux disease, and obstructive sleep apnea who presented to the emergency department on 26 December 2020 with a three day history of exertional shortness of breath and chest tightness. He presented to the emergency department when he began to experience shortness of breath and chest tightness at rest. Chest x-ray was unremarkable. ECG showed right bundle branch block consistent with a prior ECG. Resting echocardiography was unremarkable. Stress echocardiogram was positive for myocardial ischemia in the mid-left anterior descending artery distribution accompanied by anginal chest pain and a hypertensive response to exercise. He was then taken to the cardiac catheterization lab where he underwent right and left coronary angiography, intravascular ultrasound of the left anterior descending artery, and percutaneous intervention with a drug eluting stent placed into the left anterior descending coronary artery. He was found to have a 99% mid-left anterior descending artery lesion and a 70% proximal left anterior descending coronary artery lesion. Both lesions were stented. He was started on clopidogrel 75 mg daily and continued therapy with one baby aspirin daily. Troponins stayed within the normal range. Brain natriuretic peptide was normal (5 pg/mL, ref <or = 300). The subject stated that he was not admitted to the hospital and that this was treated as an outpatient. His records support this. This is been reported as a Serious Adverse Event due to being an important medical event and, given the severity of his coronary artery lesions, would likely have been fatal without intervention.' reason for change: New Information	Angie Kean (b) (4) (b) (4)	28 Jan 2021 14:16:33

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED TO NOTIFY OFFICE OF RECENT HOSPITALIZATION. STATES THAT ON 23 DEC, 24 DEC AND 25 DEC, HE NOTICED TIGHTNESS ACROSS HIS CHEST AREA WHILE EXERCISING. DENIED ANY OTHER SYMPTOMS ON THESE DAYS. HOWEVER, ON 26 DEC 2020 HE NOTICED THIS TIGHTNESS ACROSS CHEST AREA AS WELL AS SHORTNESS OF BREATH WHILE AT REST. HE WENT TO URGENT CARE, HAD A NEGATIVE COVID SWAB AND NORMAL EKG. WAS ADVISED TO GO TO BARNES EMERGENCY DEPARTMENT FOR FURTHER TESTING. MEDICAL RECORDS HAVE BEEN REQUESTED. MEDICAL RECORDS RECEIVED SHOW, COVID-19 TESTING (RAPID PCR SWAB) ON 26 DEC 2020, RESULTED AS NEGATIVE. FURTHER INFORMATION TO FOLLOW UPON PI REVIEW.' reason for change: New Information	Angie Kean (b) (4)	28 Jan 2021 14:16:05
User opened query 'Per DM CLR: SAE Narrative = NORMAL EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4)	
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results performed in the hospital. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 22:13:50
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).	(b) (4), (b) (6)	26 Jan 2021 21:23:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results performed in the hospital. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 21:23:51
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 'updated' (Site from Safety).	Angie Kean (b) (4)	25 Jan 2021 19:24:10
	(b) (4)	
	Angie Kean (b) (4)	25 Jan 2021 19:24:04
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

1938 of 2534

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED TO NOTIFY OFFICE OF RECENT HOSPITALIZATION. STATES THAT ON 23 DEC, 24 DEC AND 25 DEC, HE NOTICED TIGHTNESS ACROSS HIS CHEST AREA WHILE EXERCISING. DENIED ANY OTHER SYMPTOMS ON THESE DAYS. HOWEVER, ON 26 DEC 2020 HE NOTICED THIS TIGHTNESS ACROSS CHEST AREA AS WELL AS SHORTNESS OF BREATH WHILE AT REST. HE WENT TO URGENT CARE, HAD A NEGATIVE COVID SWAB AND NORMAL EKG. WAS ADVISED TO GO TO BARNES EMERGENCY DEPARTMENT FOR FURTHER TESTING. MEDICAL RECORDS HAVE BEEN REQUESTED. Medical records received show, COVID-19 testing (RAPID PCR SWAB) on 26 DEC 2020, resulted as NEGATIVE. Further information to follow upon PI review.' reason for change: New Information	Angie Kean (b) (4) (b) (4)	25 Jan 2021 19:23:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results performed in the hospital. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:12:09
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).	(b) (4), (b) (6)	06 Jan 2021 16:11:49

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED TO NOTIFY OFFICE OF RECENT HOSPITALIZATION. STATES THAT ON 23 DEC, 24 DEC AND 25 DEC, HE NOTICED TIGHTNESS ACROSS HIS CHEST AREA WHILE EXERCISING. DENIED ANY OTHER SYMPTOMS ON THESE DAYS. HOWEVER, ON 26 DEC 2020 HE NOTICED THIS TIGHTNESS ACROSS CHEST AREA AS WELL AS SHORTNESS OF BREATH WHILE AT REST. HE WENT TO URGENT CARE, HAD A NEGATIVE COVID SWAB AND NORMAL EKG. WAS ADVISED TO GO TO BARNES EMERGENCY DEPARTMENT FOR FURTHER TESTING. MEDICAL RECORDS HAVE BEEN REQUESTED.'	Angie Kean (b) (4) (b) (4)	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Dec 2020 01:33:40

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 19:35:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 19:35:51
Data point term sent to Coder	System	25 Jan 2021 19:35:02
User entered 'coronary artery disease'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '04 Jan 2021'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 19:34:41

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 19:34:41

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '1'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:34:41
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 19:34:41

US3812010

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Jan 2021 19:34:41

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 16:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 16:15:53
Data point term sent to Coder	System	16 Mar 2021 16:14:36
User entered 'hypertension'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '04 Jan 2021'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:13:54

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 16:14:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 16:14:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4)	16 Mar 2021 16:14:01
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 16:13:54
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 16:13:54

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '1'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	16 Mar 2021 16:13:54
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 16:13:54

US3812010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 16:13:54

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 14:40:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 14:40:54
Data point term sent to Coder	System	17 Mar 2021 14:40:35
User entered 'worsening gastroesophageal reflux disease'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '15 Feb 2021'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:39:40

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:39:40

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '1'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:39:40
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 14:39:40

US3812010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 14:39:40

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 22:46:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 22:46:01
Data point term sent to Coder	System	17 Mar 2021 14:40:35
User entered 'allergic reaction to lisinopril'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '15 Feb 2021'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:40:14

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:40:14

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4) (b) (4)	17 Mar 2021 14:40:14

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

None

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
	(b) (4)	
Signature has been broken.	Angie Kean (b) (4)	22 Apr 2021 20:29:07
	(b) (4)	
User entered '0' reason for change: New Information	Angie Kean (b) (4)	22 Apr 2021 20:29:07
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Apr 2021 16:53:43
User entered '1' reason for change: Data Entry Error	Anya Penly (b) (4)	07 Apr 2021 16:53:43
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Apr 2021 16:53:35
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
Signature has been broken.	Angie Kean (b) (4)	22 Apr 2021 20:29:07
	(b) (4)	
User entered '1' reason for change: New Information	Angie Kean (b) (4)	22 Apr 2021 20:29:07
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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), (b) (6) Lyly Dang (b) (4)	16 Apr 2021 17:19:47 08 Apr 2021 00:45:11
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 'no conprocedure noted, therefore updated eCRF' (Site from DM). User entered '0' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	07 Apr 2021 16:54:01 07 Apr 2021 16:53:35
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). User entered '1'	(b) (4), (b) (6) Breanna Galibert (b) (4)	04 Apr 2021 13:23:31 17 Mar 2021 14:40:14

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:40:14
	(b) (4)	

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 14:40:14

US3812010

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 14:40:14

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear pain, LLT: Ear pain - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:44:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 16:44:10
Data point term sent to Coder	System	30 Mar 2021 16:43:23
User entered 'bilateral ear pain'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '16 Nov 2020'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User entered empty.	System	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '04 Dec 2020'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User entered empty.	System	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'No (N)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'I'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered '0'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User entered empty.	Angie Kean (b) (4)	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User entered '0'	System	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51
User entered 'I'	System	30 Mar 2021 16:42:23

US3812010

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:50:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:51:51

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:45:11
User closed query 'Per DM RQ: Per Diary Dose 2 Day 3 (30AUG2020), PAIN AT INJECTION SITE and UNDERARM GLAND SWELLING/TENDERNESS = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:55:10
User closed query 'Per DM RQ: Diary Dose 2 Day 2, indicates that Medication was taken for FEVER on 29AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Fever) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:55:08
Query 'Per DM RQ: Per Diary Dose 2 Day 3 (30AUG2020), PAIN AT INJECTION SITE and UNDERARM GLAND SWELLING/TENDERNESS = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Please note, log line #5 ' (Site from DM).	Angie Kean (b) (4)	30 Mar 2021 15:01:16
Query 'Per DM RQ: Diary Dose 2 Day 2, indicates that Medication was taken for FEVER on 29AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Fever) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Please note, log line #5 ' (Site from DM).	Angie Kean (b) (4)	30 Mar 2021 15:01:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

2116 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User opened query 'Per DM RQ: Per Diary Dose 2 Day 3 (30AUG2020), PAIN AT INJECTION SITE and UNDERARM GLAND SWELLING/TENDERNESS = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 15:54:25
User opened query 'Per DM RQ: Diary Dose 2 Day 2, indicates that Medication was taken for FEVER on 29AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Fever) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 15:53:39
User closed query 'Per DM CLR: Per Diary Dose 2 Day 3 (30AUG2020), PAIN AT INJECTION SITE and UNDERARM GLAND SWELLING/TENDERNESS = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 15:52:56
User closed query 'Per DM CLR: Diary Dose 2 Day 2, indicates that Medication was taken for FEVER on 29AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Fever) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 15:52:49
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:00:31

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 3 (30AUG2020), PAIN AT INJECTION SITE and UNDERARM GLAND SWELLING/TENDERNESS = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.' answered with 'OK' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:02:14
Query 'Per DM CLR: Diary Dose 2 Day 2, indicates that Medication was taken for FEVER on 29AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Fever) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'OK' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:00:44
User opened query 'Per DM CLR: Per Diary Dose 2 Day 3 (30AUG2020), PAIN AT INJECTION SITE and UNDERARM GLAND SWELLING/TENDERNESS = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 07:22:58
User opened query 'Per DM CLR: Diary Dose 2 Day 2, indicates that Medication was taken for FEVER on 29AUG2020, however, there is no corresponding Con Med recorded that matches this indication (Fever) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 07:22:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 03:09:49

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 03:12:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 03:12:47
Data point term sent to Coder	System	18 Sep 2020 03:12:14
User entered 'OMEPRAZOLE'	(b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '20'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'UN UNK 1977'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Signature has been broken.	Breanna Galibert (b) (4)	01 Mar 2021 22:18:21
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	01 Mar 2021 22:18:21
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Signature has been broken.	Breanna Galibert (b) (4)	01 Mar 2021 22:18:21
User entered '15 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4)	01 Mar 2021 22:18:21
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User entered '1'	System	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User entered '1'	System	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:44
User entered '804 (804)'	System	18 Sep 2020 03:11:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
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.	Coder Import (b) (4)	18 Sep 2020 03:13:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 03:13:44
Data point term sent to Coder	System	18 Sep 2020 03:13:14
User entered 'METFORMIN'	(b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'DIABETES MELLITUS TYPE 2'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '500'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Signature has been broken.	Breanna Galibert (b) (4)	01 Mar 2021 22:18:36
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	01 Mar 2021 22:18:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Signature has been broken.	Breanna Galibert (b) (4)	01 Mar 2021 22:18:36
User entered '28 Dec 2020' reason for change: New Information	Breanna Galibert (b) (4)	01 Mar 2021 22:18:36
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User entered '1'	System	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User entered '1'	System	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:49
User entered '804 (804)'	System	18 Sep 2020 03:12:24

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 03:14:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 03:14:42
Data point term sent to Coder	System	18 Sep 2020 03:14:15
User entered 'SIMVASTATIN'	(b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'ELEVATED CHOLESTEROL'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '20'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 16:32:52
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MED HX UPDATED ' (Site from DM).	Angie Kean (b) (4) (b) (4)	26 Oct 2020 21:13:22
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:54:56
User entered 'UN UNK 2001'	(b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Signature has been broken.	Breanna Galibert (b) (4)	01 Mar 2021 22:18:58
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	01 Mar 2021 22:18:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Signature has been broken.	Breanna Galibert (b) (4)	01 Mar 2021 22:18:58
User entered '28 Dec 2020' reason for change: New Information	Breanna Galibert (b) (4)	01 Mar 2021 22:18:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 03:14:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 03:14:07
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 03:13:58
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User entered '1'	System	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User entered '1'	System	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:58
User entered '804 (804)'	System	18 Sep 2020 03:13:58

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 03:17:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 03:17:50
Data point term sent to Coder	System	18 Sep 2020 03:16:16
User entered 'TAMSULOSIN'	(b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'BENIGN PROSTATIC HYPERPLASIA'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '.4'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 10:22:14
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	26 Oct 2020 21:14:39
User entered 'UN UNK 2019' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	26 Oct 2020 21:14:34
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:57:25
User entered 'UN UNK 2009'	(b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 03:16:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:28:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 16:28:06
Data point term sent to Coder Coding entries removed.	System lauren clement (b) (4)	08 Mar 2021 16:10:56 08 Mar 2021 16:10:14
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	17 Feb 2021 04:01:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 10:17:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 10:17:42
Data point term sent to Coder User entered 'IBUPROFEN'	System (b) (4), (b) (6)	18 Sep 2020 03:18:17 18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHE, JOINT ACHES, HEADACHE, FEVER, & INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that indicated solicited adverse reaction did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 20:59:52
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHE, JOINT ACHES, HEADACHE, FEVER, & INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that indicated solicited adverse reaction did not meet the AE reporting criteria. ' answered with 'solicited events, muscle aches, joint aches, headache, fever and pain at injection site do not meet criteria for AE' (Site from DM).	Angie Kean (b) (4) (b) (4)	30 Mar 2021 15:00:46

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHE, JOINT ACHES, HEADACHE, FEVER, & INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that indicated solicited adverse reaction did not meet the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Lyly Dang (b) (4)	30 Mar 2021 09:43:21 26 Mar 2021 19:42:31
Signature has been broken.	lauren clement (b) (4)	08 Mar 2021 16:10:14
User entered 'MUSCLE ACHE, JOINT ACHES, HEADACHE, FEVER, & INJECTION SITE PAIN' reason for change: Per Query Resolution User signature succeeded.	lauren clement (b) (4) Larkin Wadsworth (b) (4)	08 Mar 2021 16:10:14 17 Feb 2021 04:01:14
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHE, JOINT ACHES, HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHE, JOINT ACHES, HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:29:37

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHE, JOINT ACHES, HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHE, JOINT ACHES, HEADACHE did not meet the AE reporting criteria.' answered with 'UPDATED, SOLICITED EVENT. DOES NOT MEET CRITERIA FOR AE' (Site from DM).	Angie Kean (b) (4) (b) (4)	26 Oct 2020 21:16:20
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHE, JOINT ACHES, HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHE, JOINT ACHES, HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:59:49
User entered 'MUSCLE ACHE, JOINT ACHES, HEADACHE'	(b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '600'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '30 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User closed query 'Per DM CLR: Was this medication taken for solicited event=NO. however, there is a record of this event in Diary within 7-day reporting period of SAR. Review if this should be updated. Else, provide clarification' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 08:11:00
Query 'Per DM CLR: Was this medication taken for solicited event=NO. however, there is a record of this event in Diary within 7-day reporting period of SAR. Review if this should be updated. Else, provide clarification' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	26 Oct 2020 21:16:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	26 Oct 2020 21:16:05
User opened query 'Per DM CLR: Was this medication taken for solicited event=NO. however, there is a record of this event in Diary within 7-day reporting period of SAR. Review if this should be updated. Else, provide clarification' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:05:21
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User entered empty.	System	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User entered empty.	System	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:04
User entered empty.	System	18 Sep 2020 03:17:53

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
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.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:29:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:29:44
Data point term sent to Coder	System	08 Mar 2021 17:17:14
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 17:16:57
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
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.	Coder Import (b) (4) (b) (4)	30 Dec 2020 07:05:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 07:05:26
Data point term sent to Coder	System	30 Dec 2020 01:39:16
User entered 'ATORVASTATIN'	Angie Kean (b) (4) (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
	(b) (4), (b) (6)	09 Mar 2021 20:12:27
DataPoint Verified.	lauren clement (b) (4)	08 Mar 2021 17:16:57
Signature has been broken.	lauren clement (b) (4)	08 Mar 2021 17:16:57
User entered 'UNSTABLE ANGINA AND CAD' reason for change: Per Query Resolution	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User signature succeeded.	Angie Kean (b) (4)	30 Dec 2020 01:39:09
User entered 'SAE-CHEST TIGHTNESS'	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '80'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '28 Dec 2020'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:17:15
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)	09 Mar 2021 12:17:03
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'No, this medication will be ongoing throughout entire study.' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:40:19
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'SUBJECT WILL BE USING THIS MEDICATION AS ONGOING INDEFINITELY ' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:39:24
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 23:27:45
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)	23 Feb 2021 02:14:58
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:27
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Dec 2020 01:39:09

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 17:19:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 17:19:39
Data point term sent to Coder	System	08 Mar 2021 17:18:17
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 17:17:24
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	17 Feb 2021 04:01:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 15:28:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 15:28:16
Data point term sent to Coder	System	30 Dec 2020 15:27:36
User entered 'PLAVIX'	Angie Kean (b) (4) (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
Signature has been broken.	lauren clement (b) (4)	08 Mar 2021 17:17:24
User entered 'UNSTABLE ANGINA AND CAD' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 17:17:24
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered 'CHEST TIGHTNESS AE#3'	Angie Kean (b) (4)	30 Dec 2020 15:27:15
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '75'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '28 Dec 2020'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:18:29
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)	09 Mar 2021 12:18:25
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'no, keep as ongoing' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:42:54
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 'Subject will be on this for awhile, continue as ongoing.' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:42:39
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 23:29:57
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)	23 Feb 2021 02:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:30
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Dec 2020 15:27:15

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:15:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:15:02
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
Data point term sent to Coder Coding entries removed.	System lauren clement (b) (4)	08 Mar 2021 17:18:19 08 Mar 2021 17:18:00
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	17 Feb 2021 04:01:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:22:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:22:17
Data point term sent to Coder	System	30 Dec 2020 15:28:37
User entered 'ISOSORBIDE/MONONITRATE ER'	Angie Kean (b) (4) (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
	(b) (4)	
Signature has been broken.	lauren clement (b) (4)	08 Mar 2021 17:18:00
	(b) (4)	
User entered 'UNSTABLE ANGINA AND CAD' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 17:18:00
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered 'CHEST TIGHTNESS/ AE #3'	Angie Kean (b) (4)	30 Dec 2020 15:27:57
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '30'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '28 Dec 2020'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:19:11
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)	09 Mar 2021 12:19:01
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'No, keep as ongoing' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:45:15
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 'Subject reports ongoing during day 209 visit. Will be on this medication for awhile.' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 16:45:09
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 23:30:15
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)	23 Feb 2021 02:15:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Dec 2020 15:27:57

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:56:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:56:56
Data point term sent to Coder Coding entries removed.	System lauren clement (b) (4)	08 Mar 2021 17:19:20 08 Mar 2021 17:18:32
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	17 Feb 2021 04:01:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:08:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 16:08:19
Data point term sent to Coder User entered 'CARVEDILOL'	System Angie Kean (b) (4) (b) (4)	30 Dec 2020 15:29:38 30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
Signature has been broken.	lauren clement (b) (4)	08 Mar 2021 17:18:32
User entered 'UNSTABLE ANGINA AND CAD' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 17:18:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered 'CHEST TIGHTNESS/ AE#3'	Angie Kean (b) (4)	30 Dec 2020 15:29:33
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '3.125'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '28 Dec 2020'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:20:09
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)	09 Mar 2021 12:20:06
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'No, keep ongoing' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 17:14:09
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'This medication will be continuous, keep as ongoing.' (Site from DM).	lauren clement (b) (4)	08 Mar 2021 17:14:04
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 AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 23:30:33
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:15:24
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:35
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Dec 2020 15:29:33

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
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)	08 Mar 2021 23:25:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:25:43
Data point term sent to Coder	System	08 Mar 2021 17:17:16
Coding entries removed.	lauren clement (b) (4)	08 Mar 2021 17:16:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
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)	25 Jan 2021 19:37:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:37:38
Data point term sent to Coder	System	25 Jan 2021 19:36:03
Data point term sent to Coder	System	25 Jan 2021 19:32:58
User entered 'aspirin'	Angie Kean (b) (4) (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4)	25 Jan 2021 19:35:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
Signature has been broken.	lauren clement (b) (4)	08 Mar 2021 17:16:16
User entered 'UNSTABLE ANGINA AND CAD' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 17:16:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered 'coronary artery disease' reason for change: Data Entry Error	Angie Kean (b) (4)	25 Jan 2021 19:35:11
	(b) (4)	
User entered 'unstable angina'	Angie Kean (b) (4)	25 Jan 2021 19:32:55
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '81'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'mg (mg)'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'once daily (QD)'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: Con Med start date is prior to the start date of the corresponding AE (04Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:24:13
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
Query 'Per CDM RQ: Con Med start date is prior to the start date of the corresponding AE (04Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' answered with 'per ae start date of UNSTABLE ANGINA is 23 DEC 2020; started taking for UNSTABLE ANGINA and then also used for CAD' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 14:58:55
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (04Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.'	(b) (4), (b) (6)	09 Mar 2021 12:21:48
' (Site from DM).		
User opened query 'Per CDM RQ: Con Med start date is prior to the start date of the corresponding AE (04Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:21:45
Reviewed for Data Management.	(b) (4), (b) (6)	09 Mar 2021 12:21:18
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (04Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.'	lauren clement (b) (4)	08 Mar 2021 17:14:52
' answered with 'ok' (Site from DM).		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (04Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.'	(b) (4), (b) (6)	23 Feb 2021 21:12:17
' (Site from DM).		

PRODUCTION RELEASE (v12.003
EAB) (1725)

2293 of 2534

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '28 Dec 2020'	Angie Kean (b) (4)	25 Jan 2021 19:32:55
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '0'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'Yes (Y)'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered empty.	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:12:38
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Angie Kean (b) (4)	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 19:32:55

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 16:07:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 16:07:43
Data point term sent to Coder User entered 'lisinopril'	System Breanna Galibert (b) (4) (b) (4)	02 Mar 2021 16:06:48 02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:28:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' answered with 'Updated AE form' (Site from DM).	Angie Kean (b) (4)	16 Mar 2021 16:13:07
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 09:16:35
User entered 'hypertension'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '10'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'mg (mg)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '04 Jan 2021' reason for change: New Information	Angie Kean (b) (4)	16 Mar 2021 16:13:14
User entered '13 Jan 2021'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '0'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '15 Feb 2021'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User entered '1'	System	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User entered '1'	System	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:20:10
User entered '804 (804)'	System	02 Mar 2021 16:06:10

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
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.	Coder Import (b) (4)	02 Mar 2021 16:07:43
User coded data point as Term Coded data point by	Coder Import (b) (4)	02 Mar 2021 16:07:43
User: Coder System - version		
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	02 Mar 2021 16:06:48
User entered 'losartan'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'hypertension'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '50'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'mg (mg)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '15 Feb 2021'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '0'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Mar 2021 16:06:37
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:06:37

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:06:37

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 16:06:37

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:41:43
Data point term sent to Coder	System	17 Mar 2021 14:41:36
User entered 'pantoprazole'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'worsening gastroesophageal reflux disease'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '40'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'mg (mg)'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '15 Feb 2021'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '0'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'No (N)'	Breanna Galibert (b) (4)	17 Mar 2021 14:41:12
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 14:41:12

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 14:41:12

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 14:41:12

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:51:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:51:47
Data point term sent to Coder	System	22 Apr 2021 20:30:31
User entered 'zyrtec'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered 'No (N)'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered 'allergic reaction to lisinopril'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered '20'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered 'mg (mg)'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered empty.	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered 'twice daily (BID)'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered empty.	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered empty.	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered '21 Apr 2021'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered '0'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered 'Yes (Y)'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered empty.	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:17:58
User entered 'No (N)'	Angie Kean (b) (4)	22 Apr 2021 20:29:47
	(b) (4)	

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 20:29:47

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 20:29:47

US3812010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:50:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 20:29:47

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:50:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:00:10
Signature has been broken.	lauren clement (b) (4)	08 Mar 2021 15:37:32
User entered 'Yes (Y)' reason for change: Per Query Resolution	lauren clement (b) (4)	08 Mar 2021 15:37:32
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 15:01:32

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:54:07
User entered '29 Dec 2020'	lauren clement (b) (4)	08 Mar 2021 15:42:07

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:54:07
User entered 'CHEST X-RAY'	lauren clement (b) (4)	08 Mar 2021 15:42:07

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:54:07
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 15:42:07

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:54:07
User entered empty.	lauren clement (b) (4)	08 Mar 2021 15:42:07

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:44
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:17:11
User entered '26 Dec 2020'	lauren clement (b) (4)	08 Mar 2021 15:42:35

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:44
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:17:11
User entered 'ECG'	lauren clement (b) (4)	08 Mar 2021 15:42:35

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:44
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:17:11
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 15:42:35

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:44
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:17:11
User entered empty.	lauren clement (b) (4)	08 Mar 2021 15:42:35

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:54
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '26 Dec 2020'	lauren clement (b) (4)	08 Mar 2021 15:43:38

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:54
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'RESTING ECHOCARDIOGRAPHY'	lauren clement (b) (4)	08 Mar 2021 15:43:38

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:54
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 15:43:38

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:03:54
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	lauren clement (b) (4)	08 Mar 2021 15:43:38

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:41:53
User entered '26 Dec 2020'	lauren clement (b) (4)	08 Mar 2021 15:47:46

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:41:53
User entered 'STRESS ECHOCARDIOGRAM'	lauren clement (b) (4)	08 Mar 2021 15:47:46

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:41:53
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 15:47:46

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:41:53
User entered empty.	lauren clement (b) (4)	08 Mar 2021 15:47:46

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:06
User entered '04 Jan 2021'	lauren clement (b) (4)	08 Mar 2021 15:48:42

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:06
User entered 'CARDIAC ECHOCARDIOGRAM'	lauren clement (b) (4)	08 Mar 2021 15:48:42

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:06
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 15:48:42

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:06
User entered empty.	lauren clement (b) (4)	08 Mar 2021 15:48:42

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:17
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:21
User entered '04 Jan 2021'	lauren clement (b) (4)	08 Mar 2021 15:51:25

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:17
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:21
User entered 'PERCUTANEOUS INTERVENTION WITH A DRUG ELUTING STENT'	lauren clement (b) (4)	08 Mar 2021 15:51:25

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:17
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	08 Mar 2021 15:51:25

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:17
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 19:58:21
User entered empty.	lauren clement (b) (4)	08 Mar 2021 15:51:25

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:24
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '04 Jan 2021'	lauren clement (b) (4)	15 Mar 2021 20:59:11

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:24
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Left Coronary Angiography'	lauren clement (b) (4)	15 Mar 2021 20:59:11

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:24
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	15 Mar 2021 20:59:11

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:24
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	lauren clement (b) (4)	15 Mar 2021 20:59:11

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:28
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '04 Jan 2021'	lauren clement (b) (4)	15 Mar 2021 20:59:51

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:28
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Right Coronary Angiography'	lauren clement (b) (4)	15 Mar 2021 20:59:51

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:28
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	15 Mar 2021 20:59:51

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:28
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	lauren clement (b) (4)	15 Mar 2021 20:59:51

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:32
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '26 Dec 2020'	lauren clement (b) (4)	15 Mar 2021 21:07:18

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:32
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'CHEST, ABDOMINAL, AND PELVIC COMPUTERIZED TOMOGRAPHY ANGIOGRAPHY'	lauren clement (b) (4)	15 Mar 2021 21:07:18

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:32
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered 'Adverse Event (AE)'	lauren clement (b) (4)	15 Mar 2021 21:07:18

US3812010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:50:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:04:32
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered empty.	lauren clement (b) (4)	15 Mar 2021 21:07:18

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'USA-US111-2020-MRNA-1273-P301000024'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'lauren'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Larkin'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'clement'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Wadsworth'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '711 Old Ballas Rd Suite 105'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang(b) (4)	26 Mar 2021 19:42:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'St Louis'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'MO'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '63141'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'US'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:39:28
User entered '5'	System	16 Mar 2021 16:12:39
User entered '4'	System	09 Mar 2021 17:26:31
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '3'	System	29 Jan 2021 13:30:07
User entered '2'	System	26 Jan 2021 21:24:16
User entered '1'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'USA-US111-2020-MRNA-1273-P301000024'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'lauren'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Larkin'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'clement'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Wadsworth'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '711 Old Ballas Rd Suite 105'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'St Louis'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'MO'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '63141'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'US'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:39:28
User entered '5'	System	16 Mar 2021 16:12:39
User entered '4'	System	09 Mar 2021 17:26:31
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '3'	System	29 Jan 2021 13:30:07
User entered '2'	System	26 Jan 2021 21:24:16
User entered '1'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:50:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '30/Dec/2020 11:19'	(b) (4) System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:50:16

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)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'I'	(b) (4), (b) (6)	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'USA-US111-2020-MRNA-1273-P301000024'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'lauren'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Larkin'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'clement'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Wadsworth'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '711 Old Ballas Rd Suite 105'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'St Louis'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'MO'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '63141'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'US'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:39:28
User entered '5'	System	16 Mar 2021 16:12:39
User entered '4'	System	09 Mar 2021 17:26:31
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '3'	System	29 Jan 2021 13:30:07
User entered '2'	System	26 Jan 2021 21:24:16
User entered '1'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:50:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '26/Jan/2021 21:24'	(b) (4) System	26 Jan 2021 21:24:16

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:50:16

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)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 13:29:58
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 21:24:16

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'USA-US111-2020-MRNA-1273-P301000024'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'lauren'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Larkin'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'clement'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Wadsworth'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '711 Old Ballas Rd Suite 105'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'St Louis'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'MO'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '63141'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'US'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:39:28
User entered '5'	System	16 Mar 2021 16:12:39
User entered '4'	System	09 Mar 2021 17:26:31
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '3'	System	29 Jan 2021 13:30:07
User entered '2'	System	26 Jan 2021 21:24:16
User entered '1'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:50:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered '29/Jan/2021 13:30'	(b) (4) System	29 Jan 2021 13:30:07

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:50:16

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)	09 Mar 2021 20:42:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:26:16
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 13:30:07

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'USA-US111-2020-MRNA-1273-P301000024'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'lauren'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Larkin'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'clement'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Wadsworth'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '711 Old Ballas Rd Suite 105'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'St Louis'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'MO'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '63141'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'US'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:39:28
User entered '5'	System	16 Mar 2021 16:12:39
User entered '4'	System	09 Mar 2021 17:26:31
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '3'	System	29 Jan 2021 13:30:07
User entered '2'	System	26 Jan 2021 21:24:16
User entered '1'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:50:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User entered '09/Mar/2021 11:26'	System	09 Mar 2021 17:26:31

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:50:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 17:26:31

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'USA-US111-2020-MRNA-1273-P301000024'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'lauren'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Larkin'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'clement'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Wadsworth'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '711 Old Ballas Rd Suite 105'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'St Louis'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'MO'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '63141'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'US'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:39:28
User entered '5'	System	16 Mar 2021 16:12:39
User entered '4'	System	09 Mar 2021 17:26:31
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '3'	System	29 Jan 2021 13:30:07
User entered '2'	System	26 Jan 2021 21:24:16
User entered '1'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:50:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
User entered '16/Mar/2021 12:12'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:50:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'USA-US111-2020-MRNA-1273-P301000024'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Yes (Y)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'No (N)'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'lauren'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Larkin'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered 'clement'	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'Wadsworth'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '711 Old Ballas Rd Suite 105'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered 'St Louis'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
User entered 'MO'	System	16 Mar 2021 16:12:39

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:42:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 16:14:59
Un-reviewed for Safety.	System	16 Mar 2021 16:12:39
DataPoint Un-verified.	System	16 Mar 2021 16:12:39
Signature has been broken.	System	16 Mar 2021 16:12:39
User entered empty.	System	16 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 16:18:56
User entered '63141'	System	30 Dec 2020 16:18:23

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:42:50
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:19:24
User entered 'US'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 10 Jun 2021 09:50:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Apr 2021 14:39:28
User entered '5'	System	16 Mar 2021 16:12:39
User entered '4'	System	09 Mar 2021 17:26:31
User signature succeeded.	Larkin Wadsworth (b) (4)	17 Feb 2021 04:01:14
	(b) (4)	
User entered '3'	System	29 Jan 2021 13:30:07
User entered '2'	System	26 Jan 2021 21:24:16
User entered '1'	System	30 Dec 2020 16:19:08

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:50:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:25:42
User entered '08/Apr/2021 09:39'	System	08 Apr 2021 14:39:28

US3812010

Folder: SAE USA-US111-2020-MRNA-1273-P301000024

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:50:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 16:25:42
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 14:39:28