

US3882011 (Prod: VA Greater Los Angeles Healthcare - NAVREF)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:16:35

All time stamps listed in this document are displayed in GMT

US3882011

Form: Participant Creation

Data signed: (b) (4) 03 Sep 2020 03:28:52

Generated On: 10 Jun 2021 10:16:35

Participant ID

US3882011

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

US3882011

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3882011

Folder: Screening

Form: Demographics

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3882011

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Date of Informed Consent (*dd MMM yyyy*) 2 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

US3882011

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3882011

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Nov 2020 23:14:17

Generated On: 10 Jun 2021 10:16:35

Were any significant conditions reported?

Yes ☒

No ☐

US3882011

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	METHAMPHETAMINE DEPENDENCE
Start date (dd MMM yyyy)	02 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3882011

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	TINNITUS
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3882011

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	MOOD DISORDER; DEPRESSION AND ANXIETY
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	OSTEOARTHRITIS OF KNEE
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	DENTAL CARIES
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	HEARING LOSS
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	HTN - HYPERTENSION
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	NONDEPENDENT CANNABIS ABUSE
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	TOBACCO USER
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	CHRONIC LOW BACK PAIN
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	MIXED HYPERLIPIDEMIA
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3882011

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	HOMELESS
Start date (dd MMM yyyy)	14 FEB 2018
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)	
Stop date completely unknown	True
Start Month and Year (derived)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	OBESITY
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	14 FEB 2018
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)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3882011

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Dec 2020 21:52:52

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 14:14
Height (xxx.x)	73 in
Weight (xxx.x)	330 lb
BMI (xxx.x)	43.62929 kg/m ²
BMI units	KG/M2
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3882011

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3882011

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3882011

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

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)	True
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	

US3882011

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Nov 2020 23:14:17

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Sep 2020 23:44:05

Generated On: 10 Jun 2021 10:16:35

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

What was the participant's randomization number? 145208

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 11 Nov 2020 00:32:32

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 11 Nov 2020 00:32:32

Generated On: 10 Jun 2021 10:16:35

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)	3 SEP 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 13:30
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 11 Nov 2020 00:32:32

Generated On: 10 Jun 2021 10:16:35

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)	3 SEP 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3882011

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Sep 2020 22:50:04

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:22 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3882011

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	13:58 (24 HR)
Collection date and time (derived)	3 SEP 2020 13:58

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 03 Sep 2020 22:15:43

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:45	3 SEP 2020 13:45
Nasopharyngeal Swab 2	No		

US3882011

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 22:50:04

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:44

PC Open Date & Time

03 SEP 2020 14:42

PC Close Date & Time

03 SEP 2020 17:12

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 03 SEP 2020 18:07

PC Close Date & Time 04 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:34

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 SEP 2020 15:46

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 16:59

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

08 SEP 2020 12:06

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 17:04

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 SEP 2020 14:45

PC Open Date & Time

03 SEP 2020 14:42

PC Close Date & Time

03 SEP 2020 17:12

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

03 SEP 2020 18:07

PC Close Date & Time

04 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 15:48

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 SEP 2020 16:59

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 SEP 2020 12:06

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 SEP 2020 17:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 14:45
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PC Open Date & Time	03 SEP 2020 14:42
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PC Close Date & Time	03 SEP 2020 17:12
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US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 18:07

PC Close Date & Time

04 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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)

57 of 1640

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 16:36
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

59 of 1640

EAB) (1725)

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 1640

EAB) (1725)

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 15:48
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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)

63 of 1640

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:00
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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)

65 of 1640

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:07
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

67 of 1640

EAB) (1725)

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 17:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3882011

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Sep 2020 16:02:01

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3882011

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Sep 2020 16:02:00

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Nov 2020 23:14:17

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3882011

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 16:56:48

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 16:56:49

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3882011

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 16:56:48

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

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)	2 OCT 2020
Time of assessment (00:00-23:59)	13:49 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 13:49
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	171 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	106 mmHg
Diastolic Blood Pressure units	MMHG

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

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)	2 OCT 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 15:35
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	106 mmHg
Diastolic Blood Pressure units	MMHG

US3882011

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 OCT 2020

What was the treatment time? (00:00-23:59) 15:05 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 15:05

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

US3882011

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	13:55 (24 HR)
Collection date and time (derived)	2 OCT 2020 13:55

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:52	2 OCT 2020 13:52
Nasopharyngeal Swab 2	No		

US3882011

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 03 Oct 2020 02:02:34

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

98.7 °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

02 OCT 2020 16:48

PC Open Date & Time

02 OCT 2020 15:25

PC Close Date & Time

02 OCT 2020 17:55

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	03 OCT 2020 07:30
PC Open Date & Time	02 OCT 2020 18:50
PC Close Date & Time	03 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

04 OCT 2020 11:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

98.2 °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

04 OCT 2020 16:43

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

05 OCT 2020 17:35

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 12:02

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 16:17

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 15:50

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

02 OCT 2020 16:48

PC Open Date & Time

02 OCT 2020 15:25

PC Close Date & Time

02 OCT 2020 17:55

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 OCT 2020 07:30

PC Open Date & Time

02 OCT 2020 18:50

PC Close Date & Time

03 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 11:37

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 16:44

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 17:35

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 12:02

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 16:17

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 15:51

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 16:49
PC Open Date & Time	02 OCT 2020 15:25
PC Close Date & Time	02 OCT 2020 17:55

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	03 OCT 2020 07:31
PC Open Date & Time	02 OCT 2020 18:50
PC Close Date & Time	03 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 11:38
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

105 of 1640

EAB) (1725)

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 16:44
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:36
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:03
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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)

111 of 1640

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 16:17
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 15:51
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3882011

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Oct 2020 23:48:00

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3882011

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Oct 2020 23:48:00

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Oct 2020 23:11:57

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3882011

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Oct 2020 23:11:57

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 30 Oct 2020 01:10:11

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3882011

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 01:10:11

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Oct 2020 01:10:11

Generated On: 10 Jun 2021 10:16:35

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

Visit date (dd MMM yyyy)	27 OCT 2020
--------------------------	-------------

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

Folder OID	VISIT3
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US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Oct 2020 01:10:11

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 12:30
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3882011

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Oct 2020 01:10:11

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3882011

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Oct 2020 01:10:11

Generated On: 10 Jun 2021 10:16:35

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

Collection date (dd MMM yyyy)	27 OCT 2020
-------------------------------	-------------

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

Collection date and time (derived)	27 OCT 2020 13:00
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US3882011

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 30 Oct 2020 01:10:11

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 NOV 2020 19:08:06

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

18 NOV 2020 04:38:52

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 07:06:59

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<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"/>

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 15:03:53

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

27 DEC 2020 15:27:39

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3882011

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Dec 2020 01:39:48

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 DEC 2020

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

Comments
If Contact Not Made, please provide Comments

REPORTS STOMACH FLU X 1
WEEK, STARTED 2 WEEKS AGO.
STARTED MEDICATIONS
IMMODIUM PRN FOR
DIARRHEA AND
ONDANSETRON PRN FOR
NAUSEA. DENIES FEVER OR
CHILLS. PCR NASAL SWAB
NEGATIVE ON 12/01

US3882011

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Nov 2020 18:49:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Jan 2021 04:08:01

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3882011

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Jan 2021 04:08:01

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3882011

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 07 Dec 2020 01:39:48

Generated On: 10 Jun 2021 10:16:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Feb 2021 04:28:48

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

STOMACH FLU

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)

3 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

146 of 1640

EAB) (1725)

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Feb 2021 04:28:48

Generated On: 10 Jun 2021 10:16:35

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

Action taken with investigational product None ☐
Dose Delayed ☐
Investigational Product ☐
Withdrawn ☐
Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal ☐
Not Recovered/Not Resolved ☐
Recovered/Resolved ☒
Recovered/Resolved with Sequelae ☐
Recovering/Resolving ☐
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative REPORTS STOMACH FLU X 1
WEEK, STARTED 2 WEEKS AGO.
STARTED MEDICATIONS
IMMODIUM PRN FOR
DIARRHEA AND
ONDANSETRON PRN FOR
NAUSEA. DENIES FEVER OR
CHILLS. PCR NASAL SWAB
NEGATIVE ON 12/01

PRODUCTION RELEASE (v12.003
EAB) (1725)

147 of 1640

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Feb 2021 04:28:48

Generated On: 10 Jun 2021 10:16:35

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

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Feb 2021 04:28:48

Generated On: 10 Jun 2021 10:16:35

AEID	USA-US095-2021-MRNA-1273-P30 1000002
Adverse event	SEIZURE
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)	6 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 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 type="radio"/> Grade 4 <input checked="" 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	True
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)

149 of 1640

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Feb 2021 04:28:48

Generated On: 10 Jun 2021 10:16:35

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

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Feb 2021 04:28:48

Generated On: 10 Jun 2021 10:16:35

SUBJECT (b) (6)	
	AT (b) (6)
(b) (6) WAS NOTIFIED THAT SUBJECT WAS EXPERIENCING CHEST PAIN 10/10 RADIATING TO SHOULDER BLADES. EMTS WERE CALLED AND THEY PERFORMED EKG WITH NORMAL SINUS RHYTHM. AS THE SUBJECT ATTEMPTED TO SIT UP THEY WENT INTO A SEIZURE. EMTS TRANSPORTED SUBJECT TO ER WHERE THE SUBJECT PASSED AWAY	
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)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Sep 2020 23:44:05

Generated On: 10 Jun 2021 10:16:35

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

Yes ☒

No ☐

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

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication GENERAL BODY PAIN

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)

153 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
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)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR HEALTH PROMOTION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

155 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
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"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication DULOXETINE HCL N06AX

Prophylaxis Yes ☐
No ☒

Indication MOOD - DEPRESSION

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)

157 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
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"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENTATION

Dose per administration 1000

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)

159 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
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"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication HYDROXYZINE HCL

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

161 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERAL BODY 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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

163 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication LEVOTHYROXINE NA

Prophylaxis Yes ☐
No ☒

Indication THYROID/HYPOTHYROIDISM

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

165 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
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"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HIGH BLOOD PRESSURE

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)

167 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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) _____		
Start date completely unknown		True
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"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL
(HYPERLIPIDEMIA)

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)

169 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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)		
Start date completely unknown		True
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"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication VARENICILINE

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

171 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

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

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication LOPERAMIDE

Prophylaxis Yes ☐
No ☒

Indication STOMACH FLU WITH
DIARRHEA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

173 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication STOMACH FLU WITH NAUSEA

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

175 of 1640

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Mar 2021 23:10:53

Generated On: 10 Jun 2021 10:16:35

	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)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3882011

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Feb 2021 02:44:38

Generated On: 10 Jun 2021 10:16:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3882011

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Feb 2021 02:44:38

Generated On: 10 Jun 2021 10:16:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
6 JAN 2021	EKG	Adverse Event	

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Apr 2021 21:13:23

Generated On: 10 Jun 2021 10:16:35

Date of study discontinuation/completion (dd MMM yyyy) 6 JAN 2021

Reason for discontinuation

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

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	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 6 JAN 2021

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input checked="" type="checkbox"/>

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 20:01:37

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US095-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 20:01:37

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US095-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/JAN/2021 20:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 20:01:37

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US095-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/JAN/2021 16:04
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

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 20:01:37

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US095-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	29/JAN/2021 10:36
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

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 20:01:37

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US095-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	LEWIS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/FEB/2021 14:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3882011 (Prod: VA Greater Los Angeles Healthcare - NAVREF)

US3882011

Form: Participant Creation

Generated On: 10 Jun 2021 10:16:35

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:16:58
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 03:28:52
User entered 'US3882011'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:44:31

US3882011

Form: Participant Creation

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 17:10:56
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 18:41:25

US3882011

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 17:10:59
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 03:28:52
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:44:32

US3882011

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 17:11:00
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Clinic (Clinic)'	Lauren Vigil (b) (4)	03 Sep 2020 18:41:25

US3882011

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'SCRN'	System	03 Sep 2020 18:41:25

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 03:28:52
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:44:33

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 03:18:38
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 03:04:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '59'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01
	(b) (4)	

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'YEARS'	System	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '59'	System	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Male (M)'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'I'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:22:55
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:01

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:05
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '2 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Sep 2020'	System	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2020'	System	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:05
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Amendment 3 (3)'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:05
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:05
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:05
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:05
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:28

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:05
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 03:28:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 21:44:32

US3882011

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	03 Sep 2020 18:42:32

US3882011

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:12:28
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:32

US3882011

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:16:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:49:46
Signature has been broken.	Suchi Tiwari (b) (4)	11 Nov 2020 02:20:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Suchi Tiwari (b) (4)	11 Nov 2020 02:20:38
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:42:41

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:27:50
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Psychiatric disorders, HLTG: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug dependence, LLT: Drug dependence - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:50:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:50:34
Data point term sent to Coder	System	11 Nov 2020 02:22:18
User entered 'Methamphetamine dependence'	Suchi Tiwari (b) (4)	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:27:51
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '02 Aug 2020'	Suchi Tiwari (b) (4)	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:27:54
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:27:55
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:27:57
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
Signature has been broken.	Lauren Vigil (b) (4)	03 Dec 2020 19:42:00
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:27:59
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Aug 2020'	System	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2020'	System	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:21:40

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:28:09
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:23:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:23:55
Data point term sent to Coder	System	11 Nov 2020 02:23:18
User entered 'Tinnitus'	Suchi Tiwari (b) (4)	11 Nov 2020 02:22:29
	(b) (4)	

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:28:11
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:28:15
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:28:17
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:28:19
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:28:20
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:22:29

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:12:30
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Mixed anxiety and depressive disorder, LLT: Mixed anxiety and depressive disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:21:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:21:04
User signature succeeded.	Michael Lewis (b) (4)	24 Nov 2020 02:07:53
Data point term sent to Coder	System	23 Nov 2020 19:43:42
Coding entries removed.	Lauren Vigil (b) (4)	23 Nov 2020 19:43:02
Signature has been broken.	(b) (4) Lauren Vigil (b) (4)	23 Nov 2020 19:43:02
User entered 'MOOD DISORDER; DEPRESSION AND ANXIETY' reason for change: Data Entry Error	(b) (4) Lauren Vigil (b) (4)	23 Nov 2020 19:43:02
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:23:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:23:55
Data point term sent to Coder	System	11 Nov 2020 02:23:18
User entered 'Depression'	Suchi Tiwari (b) (4) (b) (4)	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:12:32
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:12:33
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:12:35
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:12:38
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:12:39
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:23:04

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:24:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:24:43
Data point term sent to Coder	System	11 Nov 2020 02:24:19
User entered 'Osteoarthritis of Knee'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:23:28

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Gastrointestinal disorders, HLG: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Dental caries - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:24:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:24:43
Data point term sent to Coder	System	11 Nov 2020 02:24:19
User entered 'Dental Caries'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:24:01

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:25:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:25:44
Data point term sent to Coder	System	11 Nov 2020 02:25:20
User entered 'Hypothyroidism'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:24:30

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
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)	11 Nov 2020 02:40:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:40:50
Data point term sent to Coder	System	11 Nov 2020 02:25:20
User entered 'Hearing Loss'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:24:47

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:26:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:26:54
Data point term sent to Coder	System	11 Nov 2020 02:25:19
User entered 'HTN - Hypertension'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:02

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Nondependent abuse of cannabis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:48:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:48:45
Data point term sent to Coder	System	11 Nov 2020 02:25:19
User entered 'Nondependent Cannabis Abuse'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:18

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Tobacco user - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:27:43
Data point term sent to Coder	System	11 Nov 2020 02:26:23
User entered 'Tobacco User'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:34
	(b) (4)	

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:34

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:27:43
Data point term sent to Coder	System	11 Nov 2020 02:26:21
User entered 'Chronic Low Back Pain'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:25:50

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Congenital, familial and genetic disorders, HLG: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type V hyperlipidaemia, LLT: Mixed hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:28:43
Data point term sent to Coder	System	11 Nov 2020 02:27:23
User entered 'Mixed Hyperlipidemia'	Suchi Tiwari (b) (4)	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:26:40

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
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) (6)	22 Feb 2021 17:33:43
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.' answered with 'No medication reported for this condition.	Lauren Vigil (b) (4)	19 Feb 2021 17:00:57
Unable to update/reconcile because the patient is deceased.' (Site from DM).	(b) (4)	
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)	19 Jan 2021 09:37:22
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
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)	11 Nov 2020 02:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 02:28:43
Data point term sent to Coder	System	11 Nov 2020 02:27:24
User entered 'Diabetes Mellitus Type 2'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:01
	(b) (4)	

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:27:01

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Social circumstances, HLT: Economic and housing issues, HLT: Housing circumstances, PT: Homeless, LLT: Homeless - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:29:44
Data point term sent to Coder	System	11 Nov 2020 02:28:24
User entered 'Homeless'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'No (N)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'I'	Suchi Tiwari (b) (4)	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:27:55

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 02:29:44
Data point term sent to Coder	System	11 Nov 2020 02:28:24
User entered 'Obesity'	Suchi Tiwari (b) (4)	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '14 Feb 2018'	Suchi Tiwari (b) (4)	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered empty.	Suchi Tiwari (b) (4)	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
User entered '0'	Suchi Tiwari (b) (4)	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	11 Nov 2020 02:28:19

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 17:42:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 17:42:58
Data point term sent to Coder	System	15 Mar 2021 17:42:31
User entered 'Erectile Dysfunction'	Lauren Vigil (b) (4)	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
User entered '14 Feb 2018'	Lauren Vigil (b) (4)	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
User entered '0'	Lauren Vigil (b) (4)	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
User entered empty.	Lauren Vigil (b) (4)	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:13:10
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
User entered '0'	Lauren Vigil (b) (4)	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'Feb 2018'	System	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2018'	System	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	15 Mar 2021 17:41:45

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '2 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '14:14'	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2 Sep 2020 14:14'	System	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '73' in	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58
DataPoint set to visible.	(b) (4) System	03 Sep 2020 18:42:32

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '330' lb	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58
DataPoint set to visible.	(b) (4) System	03 Sep 2020 18:42:32

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '43.62929'	System	03 Sep 2020 18:43:58
DataPoint set to visible.	System	03 Sep 2020 18:42:32

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'kg/m2'	System	03 Sep 2020 18:43:58
DataPoint set to visible.	System	03 Sep 2020 18:42:32

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '97.5' F	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '71'	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'bpm'	System	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '16'	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'breaths/min'	System	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:47:19
User signature succeeded.	Michael Lewis (b) (4)	12 Dec 2020 21:52:52
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Dec 2020 16:50:38
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	11 Dec 2020 16:50:38
User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	11 Dec 2020 16:50:38
Query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' answered by data change (Site from System).	System	11 Dec 2020 16:50:38
User entered '121' reason for change: Data Entry Error	Lauren Vigil (b) (4)	11 Dec 2020 16:50:38
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Dec 2020 16:50:22
User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 160 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	11 Dec 2020 16:50:22
DataPoint Un-verified.	Lauren Vigil (b) (4)	11 Dec 2020 16:50:22
Signature has been broken.	Lauren Vigil (b) (4)	11 Dec 2020 16:50:22
User entered '230' reason for change: Data Entry Error	Lauren Vigil (b) (4)	11 Dec 2020 16:50:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 1640

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:21:47
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '78'	Lauren Vigil (b) (4)	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	03 Sep 2020 18:43:58

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:22:04
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 18:44:06

US3882011

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:22:04
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 12:14:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 22:21:28
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '2 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 18:44:06
	(b) (4)	

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 18:45:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 18:45:21
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	03 Sep 2020 18:45:21
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 18:45:12
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'I'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '0'	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:22
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 18:45:12

US3882011

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:17:11
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 22:21:28

US3882011

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:20
DataPoint Un-verified.	Lauren Vigil (b) (4)	11 Nov 2020 01:11:39
Signature has been broken.	(b) (4) Lauren Vigil (b) (4)	11 Nov 2020 01:11:39
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4) Lauren Vigil (b) (4)	11 Nov 2020 01:11:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:17:11
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '3 Sep 2020'	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 22:21:28

US3882011

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:17:11
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Clinic (Clinic)'	Lauren Vigil (b) (4)	03 Sep 2020 22:21:28

US3882011

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'VISIT1'	System	03 Sep 2020 22:21:28

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:17:21
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 20:49:52

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:17:24
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '145208'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 20:49:52

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:17:26
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 20:49:52

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:37
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 22:21:44

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:37
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 22:21:44

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:37
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 22:21:44

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:37
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 22:21:44

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:37
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 22:21:44

US3882011

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:37
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:19:34
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:02:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:02:55

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:52:38
DataPoint Un-verified.	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
Signature has been broken.	(b) (4) Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:20:10
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '73' in	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:52:40
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:00:48
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '330' lb	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:52:38
DataPoint Un-verified.	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
Signature has been broken.	(b) (4) Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:20:10
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '73' in	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:52:40
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:00:48
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '330' lb	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '3 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '13:30'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '3 Sep 2020 13:30'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '97.9' F	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '85'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'bpm'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '14'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'breaths/min'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '111'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:23
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '71'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:52:38
DataPoint Un-verified.	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:20:10
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '73' in	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	11 Nov 2020 00:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:52:40
Signature has been broken.	Lauren Vigil (b) (4)	10 Nov 2020 23:00:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	10 Nov 2020 23:00:48
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '330' lb	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '3 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	15 Oct 2020 01:26:57
User closed query 'Per CDM: The treatment time on the Exposure CRF is 14:22. The Vital Signs Post Dose Time of Assessment is 14:00 (which is before dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 11:10:59
Query 'Per CDM: The treatment time on the Exposure CRF is 14:22. The Vital Signs Post Dose Time of Assessment is 14:00 (which is before dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'the form has been updated' (Site from DM).	Lauren Vigil (b) (4)	06 Oct 2020 16:33:41
Signature has been broken.	Lauren Vigil (b) (4)	06 Oct 2020 16:32:57
User entered '14:55' reason for change: Data Entry Error	Lauren Vigil (b) (4)	06 Oct 2020 16:32:57
User opened query 'Per CDM: The treatment time on the Exposure CRF is 14:22. The Vital Signs Post Dose Time of Assessment is 14:00 (which is before dosing). Per protocol, post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:59:16
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '14:00'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '3 Sep 2020 14:55'	System	06 Oct 2020 16:32:57
User entered '3 Sep 2020 14:00'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '97.7' F	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '67'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'bpm'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '16'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'breaths/min'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '122'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:31:26
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '76'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	03 Sep 2020 22:25:22

US3882011

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:26:12
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:29

US3882011

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:26:12
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered '3 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 22:25:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:26:45
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:27:04
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:27:04
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:26:48
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '3 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:26:50
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '14:22'	Lauren Vigil (b) (4)	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '3 Sep 2020 14:22'	System	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:26:53
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Left Arm (LEFT ARM)'	Lauren Vigil (b) (4)	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:26:54
User entered 'ONCE'	System	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 21:28:29

US3882011

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:27:38
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 21:28:50

US3882011

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:27:38
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '3 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 21:28:50

US3882011

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:27:38
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '13:58'	Lauren Vigil (b) (4)	03 Sep 2020 21:28:50

US3882011

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '3 Sep 2020 13:58'	System	03 Sep 2020 21:28:50

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:54
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '3 Sep 2020'	Lauren Vigil (b) (4)	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:14:50
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:14:50
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered '13:45'	Lauren Vigil (b) (4)	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '3 Sep 2020 13:45'	System	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Vigil (b) (4) (b) (4)	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:14:50
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:14:50
User signature succeeded.	Michael Lewis (b) (4)	03 Sep 2020 22:15:44
User entered empty.	Lauren Vigil (b) (4)	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	03 Sep 2020 21:29:56

US3882011

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:24:44
User signature succeeded.	Michael Lewis (b) (4)	05 Sep 2020 22:50:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Sep 2020 22:26:12

US3882011

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	03 Sep 2020 22:26:12

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:43:26', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3cbe1d63-cc8c-4b7c-b7f5-c0b593ab2944' User entered 'Yes (Y)'	System	03 Sep 2020 21:44:10
	System	03 Sep 2020 21:44:10

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:43:43', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3cbe1d63-cc8c-4b7c-b7f5-c0b593ab2944' User entered '97.6'	System	03 Sep 2020 21:44:10
	System	03 Sep 2020 21:44:10

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:43:57', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3cbe1d63-cc8c-4b7c-b7f5-c0b593ab2944'	System	03 Sep 2020 21:44:10
User entered 'No (N)'	System	03 Sep 2020 21:44:10

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:44:07', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3cbe1d63-cc8c-4b7c-b7f5-c0b593ab2944'	System	03 Sep 2020 21:44:10
User entered '03 Sep 2020 14:44'	System	03 Sep 2020 21:44:10

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Sep 2020 14:42'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Sep 2020 17:12'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Sep 2020 18:07'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 2'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:34:03', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1283f8c0-1473-4913-ab92-1184bb328954' User entered 'Yes (Y)'	System	04 Sep 2020 23:34:33
	System	04 Sep 2020 23:34:33

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:34:11', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1283f8c0-1473-4913-ab92-1184bb328954' User entered '97.6'	System	04 Sep 2020 23:34:33
	System	04 Sep 2020 23:34:33

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:34:19', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1283f8c0-1473-4913-ab92-1184bb328954'	System	04 Sep 2020 23:34:33
User entered 'No (N)'	System	04 Sep 2020 23:34:33

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:34:30', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1283f8c0-1473-4913-ab92-1184bb328954' User entered '04 Sep 2020 16:34'	System	04 Sep 2020 23:34:33
	System	04 Sep 2020 23:34:33

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 3'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 4'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:46:37', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0aa7650a-7ba8-4364-8768-56190b77bfcc' User entered 'Yes (Y)'	System	06 Sep 2020 22:46:57
	System	06 Sep 2020 22:46:57

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:46:45', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0aa7650a-7ba8-4364-8768-56190b77bfcc' User entered '98.7'	System	06 Sep 2020 22:46:57
	System	06 Sep 2020 22:46:57

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:46:51', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0aa7650a-7ba8-4364-8768-56190b77bfcc' User entered 'No (N)'	System	06 Sep 2020 22:46:57
	System	06 Sep 2020 22:46:57

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:46:55', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0aa7650a-7ba8-4364-8768-56190b77bfcc' User entered '06 Sep 2020 15:46'	System	06 Sep 2020 22:46:57
	System	06 Sep 2020 22:46:57

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 5'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:58:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0a1f913b-03cc-4ee2-8c37-34a62940846d' User entered 'Yes (Y)'	System	07 Sep 2020 23:59:24
	System	07 Sep 2020 23:59:24

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:13', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0a1f913b-03cc-4ee2-8c37-34a62940846d' User entered '97.8'	System	07 Sep 2020 23:59:24
	System	07 Sep 2020 23:59:24

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:19', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0a1f913b-03cc-4ee2-8c37-34a62940846d' User entered 'No (N)'	System	07 Sep 2020 23:59:24
	System	07 Sep 2020 23:59:24

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:22', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0a1f913b-03cc-4ee2-8c37-34a62940846d' User entered '07 Sep 2020 16:59'	System	07 Sep 2020 23:59:24
	System	07 Sep 2020 23:59:24

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 6'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:28', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '28578430-4694-427f-b5e3-139681139de1' User entered 'Yes (Y)'	System	08 Sep 2020 19:06:47
	System	08 Sep 2020 19:06:47

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:36', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '28578430-4694-427f-b5e3-139681139de1' User entered '97.8'	System	08 Sep 2020 19:06:47
	System	08 Sep 2020 19:06:47

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:40', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '28578430-4694-427f-b5e3-139681139de1' User entered 'No (N)'	System	08 Sep 2020 19:06:47
	System	08 Sep 2020 19:06:47

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:43', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '28578430-4694-427f-b5e3-139681139de1' User entered '08 Sep 2020 12:06'	System	08 Sep 2020 19:06:47
	System	08 Sep 2020 19:06:47

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 7'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:30', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e86d84c4-8c61-44c8-9d4e-fa321141e0e4' User entered 'Yes (Y)'	System	10 Sep 2020 00:04:48
	System	10 Sep 2020 00:04:48

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:38', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e86d84c4-8c61-44c8-9d4e-fa321141e0e4' User entered '97.6'	System	10 Sep 2020 00:04:48
	System	10 Sep 2020 00:04:48

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:43', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e86d84c4-8c61-44c8-9d4e-fa321141e0e4' User entered 'No (N)'	System	10 Sep 2020 00:04:48
	System	10 Sep 2020 00:04:48

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e86d84c4-8c61-44c8-9d4e-fa321141e0e4' User entered '09 Sep 2020 17:04'	System	10 Sep 2020 00:04:48
	System	10 Sep 2020 00:04:48

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:44:32', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f50c2941-1440-4747-83bd-912697d1c53b'	System	03 Sep 2020 21:45:04
User entered 'None (1)'	System	03 Sep 2020 21:45:04

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:44:42', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f50c2941-1440-4747-83bd-912697d1c53b' User entered 'No (N)'	System	03 Sep 2020 21:45:04
	System	03 Sep 2020 21:45:04

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:44:52', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f50c2941-1440-4747-83bd-912697d1c53b' User entered 'No (N)'	System	03 Sep 2020 21:45:04
	System	03 Sep 2020 21:45:04

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:44:56', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f50c2941-1440-4747-83bd-912697d1c53b' User entered 'None (1)'	System	03 Sep 2020 21:45:04
	System	03 Sep 2020 21:45:04

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:00', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f50c2941-1440-4747-83bd-912697d1c53b' User entered '03 Sep 2020 14:45'	System	03 Sep 2020 21:45:04
	System	03 Sep 2020 21:45:04

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '03 Sep 2020 14:42'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '03 Sep 2020 17:12'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '03 Sep 2020 18:07'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 2'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:34:56', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3ed7e6c5-5a9e-4498-abc4-fffb08a98e8b'	System	04 Sep 2020 23:35:18
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 23:35:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:00', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3ed7e6c5-5a9e-4498-abc4-fffb08a98e8b' User entered 'No (N)'	System	04 Sep 2020 23:35:18
	System	04 Sep 2020 23:35:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:05', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3ed7e6c5-5a9e-4498-abc4-fffb08a98e8b' User entered 'No (N)'	System	04 Sep 2020 23:35:18
	System	04 Sep 2020 23:35:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:09', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3ed7e6c5-5a9e-4498-abc4-fffb08a98e8b' User entered 'None (1)'	System	04 Sep 2020 23:35:18
	System	04 Sep 2020 23:35:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:14', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3ed7e6c5-5a9e-4498-abc4-fffb08a98e8b' User entered '04 Sep 2020 16:35'	System	04 Sep 2020 23:35:18
	System	04 Sep 2020 23:35:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 3'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 4'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:47:01', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e2c25471-748e-49b6-a666-d9282f456e59'	System	06 Sep 2020 22:48:18
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 22:48:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:47:05', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e2c25471-748e-49b6-a666-d9282f456e59' User entered 'No (N)'	System	06 Sep 2020 22:48:18
	System	06 Sep 2020 22:48:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:47:10', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e2c25471-748e-49b6-a666-d9282f456e59' User entered 'No (N)'	System	06 Sep 2020 22:48:18
	System	06 Sep 2020 22:48:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:47:14', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e2c25471-748e-49b6-a666-d9282f456e59'	System	06 Sep 2020 22:48:18
User entered 'None (1)'	System	06 Sep 2020 22:48:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:15', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e2c25471-748e-49b6-a666-d9282f456e59' User entered '06 Sep 2020 15:48'	System	06 Sep 2020 22:48:18
	System	06 Sep 2020 22:48:18

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 5'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:27', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1c7bcb65-12cb-498a-9ad6-fdd1c0662465'	System	07 Sep 2020 23:59:43
User entered 'None (1)'	System	07 Sep 2020 23:59:43

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:30', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1c7bcb65-12cb-498a-9ad6-fdd1c0662465' User entered 'No (N)'	System	07 Sep 2020 23:59:43
	System	07 Sep 2020 23:59:43

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:32', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1c7bcb65-12cb-498a-9ad6-fdd1c0662465' User entered 'No (N)'	System	07 Sep 2020 23:59:43
	System	07 Sep 2020 23:59:43

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:35', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1c7bcb65-12cb-498a-9ad6-fdd1c0662465'	System	07 Sep 2020 23:59:43
User entered 'None (1)'	System	07 Sep 2020 23:59:43

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:38', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1c7bcb65-12cb-498a-9ad6-fdd1c0662465' User entered '07 Sep 2020 16:59'	System	07 Sep 2020 23:59:43
	System	07 Sep 2020 23:59:43

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 6'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:47', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '83f9e9fd-c838-43da-8871-e40c56337cb7' User entered 'None (1)'	System	08 Sep 2020 19:07:00
	System	08 Sep 2020 19:07:00

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:50', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '83f9e9fd-c838-43da-8871-e40c56337cb7' User entered 'No (N)'	System	08 Sep 2020 19:07:00
	System	08 Sep 2020 19:07:00

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:52', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '83f9e9fd-c838-43da-8871-e40c56337cb7' User entered 'No (N)'	System	08 Sep 2020 19:07:00
	System	08 Sep 2020 19:07:00

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '83f9e9fd-c838-43da-8871-e40c56337cb7' User entered 'None (1)'	System	08 Sep 2020 19:07:00
	System	08 Sep 2020 19:07:00

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:06:57', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '83f9e9fd-c838-43da-8871-e40c56337cb7' User entered '08 Sep 2020 12:06'	System	08 Sep 2020 19:07:00
	System	08 Sep 2020 19:07:00

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 7'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:51', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c3239d96-6c35-4e74-9ae6-60e277439444' User entered 'None (1)'	System	10 Sep 2020 00:05:07
	System	10 Sep 2020 00:05:07

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c3239d96-6c35-4e74-9ae6-60e277439444' User entered 'No (N)'	System	10 Sep 2020 00:05:07
	System	10 Sep 2020 00:05:07

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:56', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c3239d96-6c35-4e74-9ae6-60e277439444' User entered 'No (N)'	System	10 Sep 2020 00:05:07
	System	10 Sep 2020 00:05:07

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:04:58', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c3239d96-6c35-4e74-9ae6-60e277439444'	System	10 Sep 2020 00:05:07
User entered 'None (1)'	System	10 Sep 2020 00:05:07

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:01', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c3239d96-6c35-4e74-9ae6-60e277439444' User entered '09 Sep 2020 17:05'	System	10 Sep 2020 00:05:07
	System	10 Sep 2020 00:05:07

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:10', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered 'None (0)'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:16', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered 'None (0)'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:22', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered 'None (0)'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:27', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered 'None (0)'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:31', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered 'None (0)'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:34', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered 'None (0)'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:40', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered 'No (N)'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-03T14:45:42', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '180f6b2e-1b4c-4b66-aa36-a747b6c224d9' User entered '03 Sep 2020 14:45'	System	03 Sep 2020 21:45:45
	System	03 Sep 2020 21:45:45

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '03 Sep 2020 14:42'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '03 Sep 2020 17:12'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '03 Sep 2020 18:07'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 2'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:21', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b' User entered 'None (0)'	System	04 Sep 2020 23:36:30
	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:35', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b'	System	04 Sep 2020 23:36:30
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b'	System	04 Sep 2020 23:36:30
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:35:53', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b' User entered 'None (0)'	System	04 Sep 2020 23:36:30
	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:36:16', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b' User entered 'None (0)'	System	04 Sep 2020 23:36:30
	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:36:21', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b' User entered 'None (0)'	System	04 Sep 2020 23:36:30
	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:36:25', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b' User entered 'No (N)'	System	04 Sep 2020 23:36:30
	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-04T16:36:28', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '4bb28642-f1d2-4e49-98c5-cfbcc4577f3b' User entered '04 Sep 2020 16:36'	System	04 Sep 2020 23:36:30
	System	04 Sep 2020 23:36:30

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 3'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 4'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:22', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered 'None (0)'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:33', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered 'None (0)'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:42', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered 'None (0)'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered 'None (0)'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:50', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered 'None (0)'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:53', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered 'None (0)'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:57', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered 'No (N)'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-06T15:48:59', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '23200148-f148-46c5-ae99-64e23ff452fb' User entered '06 Sep 2020 15:48'	System	06 Sep 2020 22:49:01
	System	06 Sep 2020 22:49:01

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 5'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:43', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered 'None (0)'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered 'None (0)'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:49', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered 'None (0)'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:51', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered 'None (0)'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered 'None (0)'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T16:59:56', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered 'None (0)'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T17:00:00', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered 'No (N)'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-07T17:00:02', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a22ea52f-a8ba-4bc3-8b44-b0e21e224e9a' User entered '07 Sep 2020 17:00'	System	08 Sep 2020 00:00:08
	System	08 Sep 2020 00:00:08

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 6'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:02', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered 'None (0)'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:04', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered 'None (0)'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:06', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered 'None (0)'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:09', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered 'None (0)'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:12', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered 'None (0)'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:14', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered 'None (0)'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:18', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered 'No (N)'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-08T12:07:23', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '3e8ba198-e15e-44da-847c-2470797ddb83' User entered '08 Sep 2020 12:07'	System	08 Sep 2020 19:07:25
	System	08 Sep 2020 19:07:25

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 7'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:05', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered 'None (0)'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:08', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered 'None (0)'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:10', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered 'None (0)'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:12', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered 'None (0)'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:14', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered 'None (0)'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:16', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered 'None (0)'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:20', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered 'No (N)'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-09-09T17:05:23', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'd5de59b1-ba07-4578-ba34-8e608f16b4ac' User entered '09 Sep 2020 17:05'	System	10 Sep 2020 00:05:24
	System	10 Sep 2020 00:05:24

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:28:29

US3882011

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:13:00
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:02:01
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	10 Sep 2020 19:51:33

US3882011

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:13:00
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:02:01
User entered '10 Sep 2020'	Lauren Vigil (b) (4)	10 Sep 2020 19:51:33
	(b) (4)	

US3882011

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:13:00
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:02:01
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	10 Sep 2020 19:51:33

US3882011

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:13:00
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:02:01
User entered empty.	Lauren Vigil (b) (4)	10 Sep 2020 19:51:33

US3882011

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:13:11
User signature succeeded.	Michael Lewis (b) (4)	12 Sep 2020 16:02:01
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	10 Sep 2020 19:51:36

US3882011

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	10 Sep 2020 19:51:36

US3882011

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:15:20
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 20:46:44

US3882011

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:15:21
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '17 Sep 2020'	Lauren Vigil (b) (4)	22 Sep 2020 20:46:44
	(b) (4)	

US3882011

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:15:23
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	22 Sep 2020 20:46:44

US3882011

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	12 Nov 2020 23:14:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:57:32
User closed query 'Per source, contact was made on 17Sep2020. Please update comment. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 05:57:30
Query 'Per source, contact was made on 17Sep2020. Please update comment. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	05 Nov 2020 22:25:09
Signature has been broken.	Lauren Vigil (b) (4)	05 Nov 2020 22:24:48
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	05 Nov 2020 22:24:48
User opened query 'Per source, contact was made on 17Sep2020. Please update comment. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:14:48
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Contact was attempted but not made. We will continue to reach out.'	Lauren Vigil (b) (4)	22 Sep 2020 20:46:44

US3882011

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:15:30
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:56:49
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 18:25:20
	(b) (4)	

US3882011

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	24 Sep 2020 18:25:20

US3882011

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:15:43
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:56:49
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 18:53:23

US3882011

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:15:43
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:56:49
User entered '24 Sep 2020'	Lauren Vigil (b) (4)	24 Sep 2020 18:53:23
	(b) (4)	

US3882011

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:15:43
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:56:49
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	24 Sep 2020 18:53:23

US3882011

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:15:43
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:56:49
User entered empty.	Lauren Vigil (b) (4)	24 Sep 2020 18:53:23
	(b) (4)	

US3882011

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:15:50
User signature succeeded.	Michael Lewis (b) (4)	26 Sep 2020 16:56:49
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	24 Sep 2020 18:53:32

US3882011

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	24 Sep 2020 18:53:32

US3882011

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:16:05
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:10:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:16:05
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 22:10:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:16:05
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Clinic (Clinic)'	Sara Wong (b) (4)	02 Oct 2020 22:10:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'VISIT2'	System	02 Oct 2020 22:10:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Pre-Dose (PREDOSE)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '13:49'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2 Oct 2020 13:49'	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:25:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:25:29
User entered '98.7' F reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:25:29
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 22:11:13
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Oral (Oral)'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '79'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'bpm'	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '14'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'breaths/min'	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '171'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '106'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Post-Dose (POSTDOSE)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '15:35'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2 Oct 2020 15:35'	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:25:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:25:29
User entered '97.4' F reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:25:29
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 22:11:13
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Oral (Oral)'	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:25:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:25:29
User entered '71' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:25:29
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 22:11:13
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'bpm'	System	02 Oct 2020 23:25:29
User entered empty.	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:25:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:25:29
User entered '14' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:25:29
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 22:11:13
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'breaths/min'	System	02 Oct 2020 23:25:29
User entered empty.	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:25:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:25:29
User entered '164' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:25:29
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 22:11:13
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	02 Oct 2020 23:25:29
User entered empty.	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:03
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 23:25:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 23:25:29
User entered '106' reason for change: New Information	Sara Wong (b) (4)	02 Oct 2020 23:25:29
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 22:11:13
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	02 Oct 2020 23:25:29
User entered empty.	System	02 Oct 2020 22:11:13

US3882011

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:47
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:11:21

US3882011

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:17:47
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 22:11:21

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '15:05'	Sara Wong (b) (4)	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2 Oct 2020 15:05'	System	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:04
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Left Arm (LEFT ARM)'	Sara Wong (b) (4)	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:04
User entered 'ONCE'	System	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 22:12:26

US3882011

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:24
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:12:39

US3882011

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:24
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 22:12:39

US3882011

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:24
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '13:55'	Sara Wong (b) (4)	02 Oct 2020 22:12:39

US3882011

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2 Oct 2020 13:55'	System	02 Oct 2020 22:12:39

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '2 Oct 2020'	Sara Wong (b) (4)	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered '13:52'	Sara Wong (b) (4)	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2 Oct 2020 13:52'	System	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sara Wong (b) (4) (b) (4)	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'No (N)'	Sara Wong (b) (4)	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:38
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered empty.	Sara Wong (b) (4)	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	02 Oct 2020 22:12:54

US3882011

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:18:46
User signature succeeded.	Michael Lewis (b) (4)	03 Oct 2020 02:02:34
User entered 'Yes (Y)'	Sara Wong (b) (4)	02 Oct 2020 22:10:17

US3882011

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	02 Oct 2020 22:10:17

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:47:58', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '07a7882d-4b8d-4acc-996f-4957daea0809' User entered 'Yes (Y)'	System	02 Oct 2020 23:48:36
	System	02 Oct 2020 23:48:36

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:09', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '07a7882d-4b8d-4acc-996f-4957daea0809' User entered '98.7'	System	02 Oct 2020 23:48:36
	System	02 Oct 2020 23:48:36

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:17', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '07a7882d-4b8d-4acc-996f-4957daea0809' User entered 'No (N)'	System	02 Oct 2020 23:48:36
	System	02 Oct 2020 23:48:36

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:32', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '07a7882d-4b8d-4acc-996f-4957daea0809' User entered '02 Oct 2020 16:48'	System	02 Oct 2020 23:48:36
	System	02 Oct 2020 23:48:36

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 15:25'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 17:55'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:19', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '6f3e21d1-57d6-42e3-9cfc-440ed96f2265'	System	03 Oct 2020 14:30:38
User entered 'Yes (Y)'	System	03 Oct 2020 14:30:38

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:25', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '6f3e21d1-57d6-42e3-9cfc-440ed96f2265' User entered '98.2'	System	03 Oct 2020 14:30:38
	System	03 Oct 2020 14:30:38

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:33', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '6f3e21d1-57d6-42e3-9cfc-440ed96f2265'	System	03 Oct 2020 14:30:38
User entered 'No (N)'	System	03 Oct 2020 14:30:38

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:37', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '6f3e21d1-57d6-42e3-9cfc-440ed96f2265' User entered '03 Oct 2020 07:30'	System	03 Oct 2020 14:30:38
	System	03 Oct 2020 14:30:38

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 18:50'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 2'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:16', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e55d91d3-8de0-48ac-9dd2-06e5c66266b7' User entered 'Yes (Y)'	System	04 Oct 2020 18:37:31
	System	04 Oct 2020 18:37:31

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:23', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e55d91d3-8de0-48ac-9dd2-06e5c66266b7' User entered '98.2'	System	04 Oct 2020 18:37:31
	System	04 Oct 2020 18:37:31

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:25', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e55d91d3-8de0-48ac-9dd2-06e5c66266b7' User entered 'No (N)'	System	04 Oct 2020 18:37:31
	System	04 Oct 2020 18:37:31

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:29', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e55d91d3-8de0-48ac-9dd2-06e5c66266b7' User entered '04 Oct 2020 11:37'	System	04 Oct 2020 18:37:31
	System	04 Oct 2020 18:37:31

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 3'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:43:36', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '648ee669-d52e-48c8-b715-d568ce42cd01' User entered 'Yes (Y)'	System	04 Oct 2020 23:43:54
	System	04 Oct 2020 23:43:54

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:43:41', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '648ee669-d52e-48c8-b715-d568ce42cd01' User entered '98.2'	System	04 Oct 2020 23:43:54
	System	04 Oct 2020 23:43:54

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:43:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '648ee669-d52e-48c8-b715-d568ce42cd01' User entered 'No (N)'	System	04 Oct 2020 23:43:54
	System	04 Oct 2020 23:43:54

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:43:49', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '648ee669-d52e-48c8-b715-d568ce42cd01' User entered '04 Oct 2020 16:43'	System	04 Oct 2020 23:43:54
	System	04 Oct 2020 23:43:54

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 4'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:34:55', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd031ebf-d047-4099-81bd-7b70ac6d0efe' User entered 'Yes (Y)'	System	06 Oct 2020 00:35:22
	System	06 Oct 2020 00:35:22

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:10', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd031ebf-d047-4099-81bd-7b70ac6d0efe' User entered '96.8'	System	06 Oct 2020 00:35:22
	System	06 Oct 2020 00:35:22

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:14', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd031ebf-d047-4099-81bd-7b70ac6d0efe' User entered 'No (N)'	System	06 Oct 2020 00:35:22
	System	06 Oct 2020 00:35:22

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:18', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd031ebf-d047-4099-81bd-7b70ac6d0efe' User entered '05 Oct 2020 17:35'	System	06 Oct 2020 00:35:22
	System	06 Oct 2020 00:35:22

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 5'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:23', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1ea86748-76fe-4ffd-8e53-ac053b92f4d7' User entered 'Yes (Y)'	System	06 Oct 2020 19:02:42
	System	06 Oct 2020 19:02:42

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:31', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1ea86748-76fe-4ffd-8e53-ac053b92f4d7' User entered '97.6'	System	06 Oct 2020 19:02:42
	System	06 Oct 2020 19:02:42

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:34', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1ea86748-76fe-4ffd-8e53-ac053b92f4d7'	System	06 Oct 2020 19:02:42
User entered 'No (N)'	System	06 Oct 2020 19:02:42

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:37', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '1ea86748-76fe-4ffd-8e53-ac053b92f4d7' User entered '06 Oct 2020 12:02'	System	06 Oct 2020 19:02:42
	System	06 Oct 2020 19:02:42

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 6'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:01', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '890d2e23-02f8-4246-8825-3fa4c108d49a' User entered 'Yes (Y)'	System	07 Oct 2020 23:17:19
	System	07 Oct 2020 23:17:19

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:07', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '890d2e23-02f8-4246-8825-3fa4c108d49a' User entered '97.6'	System	07 Oct 2020 23:17:19
	System	07 Oct 2020 23:17:19

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:14', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '890d2e23-02f8-4246-8825-3fa4c108d49a' User entered 'No (N)'	System	07 Oct 2020 23:17:19
	System	07 Oct 2020 23:17:19

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:17', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '890d2e23-02f8-4246-8825-3fa4c108d49a' User entered '07 Oct 2020 16:17'	System	07 Oct 2020 23:17:19
	System	07 Oct 2020 23:17:19

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 7'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:50:41', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '80bfde88-e2a3-49e2-8ee6-f2a8a0884afc' User entered 'Yes (Y)'	System	08 Oct 2020 22:50:59
	System	08 Oct 2020 22:50:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:50:47', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '80bfde88-e2a3-49e2-8ee6-f2a8a0884afc' User entered '98.0'	System	08 Oct 2020 22:50:59
	System	08 Oct 2020 22:50:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:50:52', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '80bfde88-e2a3-49e2-8ee6-f2a8a0884afc'	System	08 Oct 2020 22:50:59
User entered 'No (N)'	System	08 Oct 2020 22:50:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:50:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '80bfde88-e2a3-49e2-8ee6-f2a8a0884afc' User entered '08 Oct 2020 15:50'	System	08 Oct 2020 22:50:59
	System	08 Oct 2020 22:50:59

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:44', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5a8b2e8c-13b8-46b8-8585-cd3457a81664'	System	02 Oct 2020 23:48:59
User entered 'None (1)'	System	02 Oct 2020 23:48:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:48', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5a8b2e8c-13b8-46b8-8585-cd3457a81664' User entered 'No (N)'	System	02 Oct 2020 23:48:59
	System	02 Oct 2020 23:48:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:52', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5a8b2e8c-13b8-46b8-8585-cd3457a81664' User entered 'No (N)'	System	02 Oct 2020 23:48:59
	System	02 Oct 2020 23:48:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5a8b2e8c-13b8-46b8-8585-cd3457a81664'	System	02 Oct 2020 23:48:59
User entered 'None (1)'	System	02 Oct 2020 23:48:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:48:57', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5a8b2e8c-13b8-46b8-8585-cd3457a81664' User entered '02 Oct 2020 16:48'	System	02 Oct 2020 23:48:59
	System	02 Oct 2020 23:48:59

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 15:25'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 17:55'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:41', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0c22575b-c33e-4c6f-a64b-62a146d07255'	System	03 Oct 2020 14:30:55
User entered 'None (1)'	System	03 Oct 2020 14:30:55

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:45', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0c22575b-c33e-4c6f-a64b-62a146d07255' User entered 'No (N)'	System	03 Oct 2020 14:30:55
	System	03 Oct 2020 14:30:55

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:47', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0c22575b-c33e-4c6f-a64b-62a146d07255' User entered 'No (N)'	System	03 Oct 2020 14:30:55
	System	03 Oct 2020 14:30:55

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:51', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0c22575b-c33e-4c6f-a64b-62a146d07255'	System	03 Oct 2020 14:30:55
User entered 'None (1)'	System	03 Oct 2020 14:30:55

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0c22575b-c33e-4c6f-a64b-62a146d07255' User entered '03 Oct 2020 07:30'	System	03 Oct 2020 14:30:55
	System	03 Oct 2020 14:30:55

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 18:50'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 2'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:34', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'dfc29405-b689-4948-855b-77dd3e482e9b' User entered 'None (1)'	System	04 Oct 2020 18:37:50
	System	04 Oct 2020 18:37:50

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:37', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'dfc29405-b689-4948-855b-77dd3e482e9b' User entered 'No (N)'	System	04 Oct 2020 18:37:50
	System	04 Oct 2020 18:37:50

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:42', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'dfc29405-b689-4948-855b-77dd3e482e9b' User entered 'No (N)'	System	04 Oct 2020 18:37:50
	System	04 Oct 2020 18:37:50

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:45', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'dfc29405-b689-4948-855b-77dd3e482e9b' User entered 'None (1)'	System	04 Oct 2020 18:37:50
	System	04 Oct 2020 18:37:50

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:48', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'dfc29405-b689-4948-855b-77dd3e482e9b' User entered '04 Oct 2020 11:37'	System	04 Oct 2020 18:37:50
	System	04 Oct 2020 18:37:50

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 3'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:43:56', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c2455d7f-1a41-4637-aa9a-78cdd5e28490'	System	04 Oct 2020 23:44:11
User entered 'None (1)'	System	04 Oct 2020 23:44:11

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:43:59', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c2455d7f-1a41-4637-aa9a-78cdd5e28490' User entered 'No (N)'	System	04 Oct 2020 23:44:11
	System	04 Oct 2020 23:44:11

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:03', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c2455d7f-1a41-4637-aa9a-78cdd5e28490' User entered 'No (N)'	System	04 Oct 2020 23:44:11
	System	04 Oct 2020 23:44:11

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:06', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c2455d7f-1a41-4637-aa9a-78cdd5e28490'	System	04 Oct 2020 23:44:11
User entered 'None (1)'	System	04 Oct 2020 23:44:11

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:09', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'c2455d7f-1a41-4637-aa9a-78cdd5e28490' User entered '04 Oct 2020 16:44'	System	04 Oct 2020 23:44:11
	System	04 Oct 2020 23:44:11

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 4'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:22', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '292d548d-55f3-4647-94b2-2a67dc88bdf2' User entered 'None (1)'	System	06 Oct 2020 00:35:38
	System	06 Oct 2020 00:35:38

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:27', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '292d548d-55f3-4647-94b2-2a67dc88bdf2' User entered 'No (N)'	System	06 Oct 2020 00:35:38
	System	06 Oct 2020 00:35:38

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:30', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '292d548d-55f3-4647-94b2-2a67dc88bdf2' User entered 'No (N)'	System	06 Oct 2020 00:35:38
	System	06 Oct 2020 00:35:38

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:33', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '292d548d-55f3-4647-94b2-2a67dc88bdf2' User entered 'None (1)'	System	06 Oct 2020 00:35:38
	System	06 Oct 2020 00:35:38

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:36', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '292d548d-55f3-4647-94b2-2a67dc88bdf2' User entered '05 Oct 2020 17:35'	System	06 Oct 2020 00:35:38
	System	06 Oct 2020 00:35:38

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 5'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:43', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '037c0d97-a746-4b18-a755-2c13a9c8b9a9' User entered 'None (1)'	System	06 Oct 2020 19:02:56
	System	06 Oct 2020 19:02:56

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '037c0d97-a746-4b18-a755-2c13a9c8b9a9' User entered 'No (N)'	System	06 Oct 2020 19:02:56
	System	06 Oct 2020 19:02:56

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:49', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '037c0d97-a746-4b18-a755-2c13a9c8b9a9' User entered 'No (N)'	System	06 Oct 2020 19:02:56
	System	06 Oct 2020 19:02:56

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:51', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '037c0d97-a746-4b18-a755-2c13a9c8b9a9' User entered 'None (1)'	System	06 Oct 2020 19:02:56
	System	06 Oct 2020 19:02:56

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:53', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '037c0d97-a746-4b18-a755-2c13a9c8b9a9' User entered '06 Oct 2020 12:02'	System	06 Oct 2020 19:02:56
	System	06 Oct 2020 19:02:56

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 6'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:23', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a6fad2de-e233-4d17-8623-d90bf4cb188e' User entered 'None (1)'	System	07 Oct 2020 23:17:37
	System	07 Oct 2020 23:17:37

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:26', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a6fad2de-e233-4d17-8623-d90bf4cb188e' User entered 'No (N)'	System	07 Oct 2020 23:17:37
	System	07 Oct 2020 23:17:37

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:30', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a6fad2de-e233-4d17-8623-d90bf4cb188e' User entered 'No (N)'	System	07 Oct 2020 23:17:37
	System	07 Oct 2020 23:17:37

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:33', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a6fad2de-e233-4d17-8623-d90bf4cb188e' User entered 'None (1)'	System	07 Oct 2020 23:17:37
	System	07 Oct 2020 23:17:37

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:36', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a6fad2de-e233-4d17-8623-d90bf4cb188e' User entered '07 Oct 2020 16:17'	System	07 Oct 2020 23:17:37
	System	07 Oct 2020 23:17:37

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 7'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:00', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f853dfee-ea22-4ff6-b255-e4e8231cdfa0'	System	08 Oct 2020 22:51:15
User entered 'None (1)'	System	08 Oct 2020 22:51:15

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:03', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f853dfee-ea22-4ff6-b255-e4e8231cdfa0'	System	08 Oct 2020 22:51:15
User entered 'No (N)'	System	08 Oct 2020 22:51:15

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:06', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f853dfee-ea22-4ff6-b255-e4e8231cdfa0'	System	08 Oct 2020 22:51:15
User entered 'No (N)'	System	08 Oct 2020 22:51:15

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:09', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f853dfee-ea22-4ff6-b255-e4e8231cdfa0'	System	08 Oct 2020 22:51:15
User entered 'None (1)'	System	08 Oct 2020 22:51:15

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:12', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'f853dfee-ea22-4ff6-b255-e4e8231cdfa0'	System	08 Oct 2020 22:51:15
User entered '08 Oct 2020 15:51'	System	08 Oct 2020 22:51:15

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:06', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered 'None (0)'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:09', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered 'None (0)'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:12', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered 'None (0)'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:15', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered 'None (0)'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:17', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered 'None (0)'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:19', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered 'None (0)'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:27', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered 'No (N)'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-02T16:49:29', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '90de4d18-4916-4ce4-8e9b-a1a66e01abcb' User entered '02 Oct 2020 16:49'	System	02 Oct 2020 23:49:31
	System	02 Oct 2020 23:49:31

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 15:25'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 17:55'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:30:59', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered 'None (0)'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:31:01', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered 'None (0)'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:31:03', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered 'None (0)'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:31:07', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered 'None (0)'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:31:10', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered 'None (0)'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:31:14', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered 'None (0)'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:31:18', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered 'No (N)'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-03T07:31:20', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'bc968c09-2992-48cc-a219-817bfa0c8fd5' User entered '03 Oct 2020 07:31'	System	03 Oct 2020 14:31:22
	System	03 Oct 2020 14:31:22

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '02 Oct 2020 18:50'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 2'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:55', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529' User entered 'None (0)'	System	04 Oct 2020 18:38:14
	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:37:57', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529' User entered 'None (0)'	System	04 Oct 2020 18:38:14
	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:38:00', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529' User entered 'None (0)'	System	04 Oct 2020 18:38:14
	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:38:02', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529' User entered 'None (0)'	System	04 Oct 2020 18:38:14
	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:38:05', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529' User entered 'None (0)'	System	04 Oct 2020 18:38:14
	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:38:07', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529' User entered 'None (0)'	System	04 Oct 2020 18:38:14
	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:38:10', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529'	System	04 Oct 2020 18:38:14
User entered 'No (N)'	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T11:38:13', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'fd74b386-151f-4cb0-8115-7e1989690529' User entered '04 Oct 2020 11:38'	System	04 Oct 2020 18:38:14
	System	04 Oct 2020 18:38:14

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 3'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:15', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered 'None (0)'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:17', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered 'None (0)'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:20', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered 'None (0)'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:23', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered 'None (0)'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:25', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered 'None (0)'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:27', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered 'None (0)'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:36', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered 'No (N)'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-04T16:44:39', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '024dd934-0c89-438d-ad0b-638ee4358c41' User entered '04 Oct 2020 16:44'	System	04 Oct 2020 23:44:42
	System	04 Oct 2020 23:44:42

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 4'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:40', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered 'None (0)'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:43', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered 'None (0)'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered 'None (0)'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:48', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered 'None (0)'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:50', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered 'None (0)'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:54', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered 'None (0)'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:35:59', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered 'No (N)'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-05T17:36:01', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '0beb7a3e-89c7-4e16-8fc6-bbc42125b01b' User entered '05 Oct 2020 17:36'	System	06 Oct 2020 00:36:05
	System	06 Oct 2020 00:36:05

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 5'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:02:58', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered 'None (0)'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:03:00', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered 'None (0)'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:03:02', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered 'None (0)'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:03:04', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered 'None (0)'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:03:06', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered 'None (0)'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:03:08', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered 'None (0)'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:03:11', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered 'No (N)'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-06T12:03:13', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '7f2a83e6-fec9-4de6-853c-f0a43d6e383b' User entered '06 Oct 2020 12:03'	System	06 Oct 2020 19:03:15
	System	06 Oct 2020 19:03:15

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 6'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:42', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered 'None (0)'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:44', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered 'None (0)'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:46', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered 'None (0)'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:48', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered 'None (0)'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:50', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered 'None (0)'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:53', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered 'None (0)'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:56', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered 'No (N)'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-07T16:17:59', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '5f3025cc-7459-49f5-806c-bab4d9f1324d' User entered '07 Oct 2020 16:17'	System	07 Oct 2020 23:18:04
	System	07 Oct 2020 23:18:04

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	02 Oct 2020 22:12:26
User entered 'Day 7'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:16', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered 'None (0)'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:18', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered 'None (0)'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:20', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered 'None (0)'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:22', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered 'None (0)'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:25', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered 'None (0)'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:27', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered 'None (0)'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:29', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered 'No (N)'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-10-08T15:51:31', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'a99e5e98-7e2d-49c8-a04f-4fe713a783cc' User entered '08 Oct 2020 15:51'	System	08 Oct 2020 22:51:36
	System	08 Oct 2020 22:51:36

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 22:12:26

US3882011

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 22:12:26

US3882011

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:20
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:48:00
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	09 Oct 2020 17:45:23

US3882011

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:20
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:48:00
User entered '09 Oct 2020'	Lauren Vigil (b) (4)	09 Oct 2020 17:45:23

US3882011

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:20
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:48:00
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	09 Oct 2020 17:45:23

US3882011

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:20
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:48:00
User entered empty.	Lauren Vigil (b) (4)	09 Oct 2020 17:45:23

US3882011

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:28
User signature succeeded.	Michael Lewis (b) (4)	09 Oct 2020 23:48:00
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	09 Oct 2020 17:45:51

US3882011

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	09 Oct 2020 17:45:51

US3882011

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:38
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:11:57
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	16 Oct 2020 21:50:27

US3882011

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:38
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:11:57
User entered '16 Oct 2020'	Lauren Vigil (b) (4)	16 Oct 2020 21:50:27
	(b) (4)	

US3882011

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:38
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:11:57
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	16 Oct 2020 21:50:27

US3882011

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:38
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:11:57
User entered empty.	Lauren Vigil (b) (4)	16 Oct 2020 21:50:27

US3882011

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:19:46
User signature succeeded.	Michael Lewis (b) (4)	16 Oct 2020 23:11:57
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	16 Oct 2020 21:50:33

US3882011

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	16 Oct 2020 21:50:33

US3882011

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:14
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Suchi Tiwari (b) (4)	26 Oct 2020 18:01:18

US3882011

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:14
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '26 Oct 2020'	Suchi Tiwari (b) (4)	26 Oct 2020 18:01:18

US3882011

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:14
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Contact Made (CONTACT MADE)'	Suchi Tiwari (b) (4)	26 Oct 2020 18:01:18

US3882011

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:14
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered empty.	Suchi Tiwari (b) (4)	26 Oct 2020 18:01:18

US3882011

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:21
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Oct 2020 19:00:57

US3882011

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	26 Oct 2020 19:00:57

US3882011

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:52
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Oct 2020 19:51:45

US3882011

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:52
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '27 Oct 2020'	Lauren Vigil (b) (4)	27 Oct 2020 19:51:45

US3882011

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:20:52
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Clinic (Clinic)'	Lauren Vigil (b) (4)	27 Oct 2020 19:51:45

US3882011

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'VISIT3'	System	27 Oct 2020 19:51:45

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '27 Oct 2020'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '12:30'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '27 Oct 2020 12:30'	System	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '97.8' F	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Oral (Oral)'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered empty.	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '77'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'bpm'	System	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '18'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'breaths/min'	System	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '141'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:21:31
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '87'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'mmHg'	System	27 Oct 2020 19:52:13

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:22:03
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:19

US3882011

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:22:03
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '27 Oct 2020'	Lauren Vigil (b) (4)	27 Oct 2020 19:52:19

US3882011

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:22:17
User closed query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 27OCT2020, however, per GCL, they have an Unscheduled sample collected on 27OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:19:36
Query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 27OCT2020, however, per GCL, they have an Unscheduled sample collected on 27OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' answered with 'This sample should be labeled as Visit 3 Day 57. ' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	10 Nov 2020 18:54:32
User opened query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 27OCT2020, however, per GCL, they have an Unscheduled sample collected on 27OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:03:02
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Lauren Vigil (b) (4) (b) (4)	27 Oct 2020 20:11:53

US3882011

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:22:17
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:39:23
User entered '27 Oct 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	27 Oct 2020 20:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:11:53
User entered empty.	Lauren Vigil (b) (4)	27 Oct 2020 20:11:53

US3882011

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:22:17
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:39:23
User entered '13:00' reason for change: Data Entry Error	Lauren Vigil (b) (4)	27 Oct 2020 20:39:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:11:53
User entered empty.	Lauren Vigil (b) (4)	27 Oct 2020 20:11:53

US3882011

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '27 Oct 2020 13:00'	System	27 Oct 2020 20:39:23
User entered empty.	System	27 Oct 2020 20:11:53

US3882011

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:22:25
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Oct 2020 20:38:39

US3882011

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	27 Oct 2020 20:38:39

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 64'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42
Data entry locked.	System	03 Sep 2020 21:28:29
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:59:42
Data entry locked.	System	03 Sep 2020 21:28:29
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 71'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-11T19:07:56', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '337d6e0a-d480-4c9e-a98a-8caf3e9afac2'	System	12 Nov 2020 03:08:08
User entered 'No (N)'	System	12 Nov 2020 03:08:08

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-11T19:08:00', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '337d6e0a-d480-4c9e-a98a-8caf3e9afac2'	System	12 Nov 2020 03:08:08
User entered 'No (N)'	System	12 Nov 2020 03:08:08

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-11T19:08:06', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '337d6e0a-d480-4c9e-a98a-8caf3e9afac2' User entered '11 Nov 2020 19:08:06'	System	12 Nov 2020 03:08:08
	System	12 Nov 2020 03:08:08

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered 'Day 78'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-18T04:38:42', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e5fab265-33df-4c8f-8ba2-6a2550b9d27e' User entered 'No (N)'	System	18 Nov 2020 12:38:56
	System	18 Nov 2020 12:38:56

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-18T04:38:47', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e5fab265-33df-4c8f-8ba2-6a2550b9d27e'	System	18 Nov 2020 12:38:56
User entered 'No (N)'	System	18 Nov 2020 12:38:56

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-18T04:38:52', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'e5fab265-33df-4c8f-8ba2-6a2550b9d27e' User entered '18 Nov 2020 04:38:52'	System	18 Nov 2020 12:38:56
	System	18 Nov 2020 12:38:56

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 21:28:29

US3882011

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:58:02
Data entry locked.	System	03 Sep 2020 21:28:29
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 21:28:29

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-30T07:06:48', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '6093e134-af17-42cf-b744-0fa2585ab8db' User entered 'No (N)'	System	30 Nov 2020 15:07:05
	System	30 Nov 2020 15:07:05

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-30T07:06:55', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '6093e134-af17-42cf-b744-0fa2585ab8db' User entered 'No (N)'	System	30 Nov 2020 15:07:05
	System	30 Nov 2020 15:07:05

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-11-30T07:06:59', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '6093e134-af17-42cf-b744-0fa2585ab8db' User entered '30 Nov 2020 07:06:59'	System	30 Nov 2020 15:07:05
	System	30 Nov 2020 15:07:05

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-12-12T15:03:45', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'ee2a7a36-aa59-49d8-9cdd-6536dae938f7'	System	12 Dec 2020 23:03:56
User entered 'No (N)'	System	12 Dec 2020 23:03:56

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-12-12T15:03:49', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'ee2a7a36-aa59-49d8-9cdd-6536dae938f7'	System	12 Dec 2020 23:03:56
User entered 'No (N)'	System	12 Dec 2020 23:03:56

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-12-12T15:03:53', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: 'ee2a7a36-aa59-49d8-9cdd-6536dae938f7' User entered '12 Dec 2020 15:03:53'	System	12 Dec 2020 23:03:56
	System	12 Dec 2020 23:03:56

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-12-27T15:27:30', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '9372f6e7-2312-46d1-b2af-8aa28e4ded86' User entered 'No (N)'	System	27 Dec 2020 23:27:43
	System	27 Dec 2020 23:27:43

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-12-27T15:27:35', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '9372f6e7-2312-46d1-b2af-8aa28e4ded86'	System	27 Dec 2020 23:27:43
User entered 'No (N)'	System	27 Dec 2020 23:27:43

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (443DB078-6239-4256-987D-7FA7DEDFBF51)', Time: '2020-12-27T15:27:39', User OID: 'PatientReportedOutcome (US3882011)', ODM File OID: '9372f6e7-2312-46d1-b2af-8aa28e4ded86' User entered '27 Dec 2020 15:27:39'	System	27 Dec 2020 23:27:43
	System	27 Dec 2020 23:27:43

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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)	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 02:59:42

US3882011

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:59:42
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 02:59:42

US3882011

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:03:18
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	25 Nov 2020 18:43:02

US3882011

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:03:20
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 10:43:50
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Contact was attempted but not made until this date' (Site from System).	Lauren Vigil (b) (4)	03 Dec 2020 22:07:26
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Dec 2020 19:35:49
Signature has been broken.	Lauren Vigil (b) (4)	03 Dec 2020 19:35:49
User entered '03 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	03 Dec 2020 19:35:49
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User entered '25 Nov 2020'	Lauren Vigil (b) (4)	25 Nov 2020 18:43:02

US3882011

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:03:23
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
Signature has been broken.	Lauren Vigil (b) (4)	03 Dec 2020 19:35:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Lauren Vigil (b) (4)	03 Dec 2020 19:35:49
User signature succeeded.	(b) (4)	
	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Lauren Vigil (b) (4)	25 Nov 2020 18:43:02
	(b) (4)	

US3882011

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:05:49
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
Signature has been broken.	Lauren Vigil (b) (4)	03 Dec 2020 19:35:49
User entered 'Reports stomach flu x 1 week, started 2 weeks ago.	Lauren Vigil (b) (4)	03 Dec 2020 19:35:49
Started medications immodium PRN for diarrhea and ondansetron PRN for nausea. Denies fever or chills. PCR nasal swab negative on 12/01' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	25 Nov 2020 18:44:38
Please review and reconcile.' (Site from System).		
User entered 'WILL CONTINUE TO ATTEMPT' reason for change: Data Entry Error	Lauren Vigil (b) (4)	25 Nov 2020 18:44:38
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	
Please review and reconcile.' (Site from System).	System	25 Nov 2020 18:43:02
User entered empty.	Lauren Vigil (b) (4)	25 Nov 2020 18:43:02
	(b) (4)	

US3882011

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:05:56
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	25 Nov 2020 18:43:09

US3882011

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	25 Nov 2020 18:43:09

US3882011

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:21:52
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:08:01
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Dec 2020 20:24:48

US3882011

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:21:52
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:08:01
User entered '27 Dec 2020'	Lauren Vigil (b) (4)	27 Dec 2020 20:24:48

US3882011

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:21:52
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:08:01
User entered 'Contact Made (CONTACT MADE)'	Lauren Vigil (b) (4)	27 Dec 2020 20:24:48

US3882011

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:21:52
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:08:01
User entered empty.	Lauren Vigil (b) (4)	27 Dec 2020 20:24:48

US3882011

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:22:31
User signature succeeded.	Michael Lewis (b) (4)	05 Jan 2021 04:08:01
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	27 Dec 2020 20:24:54

US3882011

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered 'I'	System	27 Dec 2020 20:24:54

US3882011

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 01:24:39
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
Signature has been broken.	Lauren Vigil (b) (4)	03 Dec 2020 22:07:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	03 Dec 2020 22:07:43
User signature succeeded.	Michael Lewis (b) (4)	19 Sep 2020 00:32:20
User entered 'No (N)'	Lauren Vigil (b) (4)	17 Sep 2020 19:10:48

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:04:14
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Gastroenteritis viral, LLT: Stomach flu - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 22:11:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 22:11:04
Data point term sent to Coder	System	03 Dec 2020 22:09:57
User entered 'STOMACH FLU'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:04:18
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:04:21
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 02:04:22
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:54:56
User signature succeeded.	Michael Lewis (b) (4)	25 Feb 2021 04:28:48
User closed query 'Per CDM re-query: Site response indicates that the CM use of NAUSEA and DIARRHEA are both related to STOMACH FLU, however, those CM start dates (16Nov) are PRIOR to AE start date (19Nov). In order to reconcile previous query, please confirm and update where necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:02:17
Query 'Per CDM re-query: Site response indicates that the CM use of NAUSEA and DIARRHEA are both related to STOMACH FLU, however, those CM start dates (16Nov) are PRIOR to AE start date (19Nov). In order to reconcile previous query, please confirm and update where necessary. Thank you.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	22 Feb 2021 21:30:24
Signature has been broken.	Lauren Vigil (b) (4)	22 Feb 2021 21:30:18
User entered '16 Nov 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4)	22 Feb 2021 21:30:18
User opened query 'Per CDM re-query: Site response indicates that the CM use of NAUSEA and DIARRHEA are both related to STOMACH FLU, however, those CM start dates (16Nov) are PRIOR to AE start date (19Nov). In order to reconcile previous query, please confirm and update where necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:05:44

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please reconcile data on this AE 'Stomach Flu' form with data on Log Lines 11 and 12 on CM forms, as it appears they are related. Kindly note, on Log Line 11 of CM medication is recorded for 'Diarrhea' with 16Nov2020 start date and 03Dec2020 end date; and on Log Line 12 of CM medication is recorded for 'Nausea' with 16Nov2020 start date and 03Dec2020 end date. Please verify if CM indications of 'Nausea' and 'Diarrhea' are related to AE 'Stomach Flu' and update all applicable forms as appropriate, including indication fields of CMs, and start and end dates of AE. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:05:44
Query 'Per CDM: Please reconcile data on this AE 'Stomach Flu' form with data on Log Lines 11 and 12 on CM forms, as it appears they are related. Kindly note, on Log Line 11 of CM medication is recorded for 'Diarrhea' with 16Nov2020 start date and 03Dec2020 end date; and on Log Line 12 of CM medication is recorded for 'Nausea' with 16Nov2020 start date and 03Dec2020 end date. Please verify if CM indications of 'Nausea' and 'Diarrhea' are related to AE 'Stomach Flu' and update all applicable forms as appropriate, including indication fields of CMs, and start and end dates of AE. Thank you.' answered with 'Nausea and diarrhea are related to the AE stomach flu.' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:48:25
User opened query 'Per CDM: Please reconcile data on this AE 'Stomach Flu' form with data on Log Lines 11 and 12 on CM forms, as it appears they are related. Kindly note, on Log Line 11 of CM medication is recorded for 'Diarrhea' with 16Nov2020 start date and 03Dec2020 end date; and on Log Line 12 of CM medication is recorded for 'Nausea' with 16Nov2020 start date and 03Dec2020 end date. Please verify if CM indications of 'Nausea' and 'Diarrhea' are related to AE 'Stomach Flu' and update all applicable forms as appropriate, including indication fields of CMs, and start and end dates of AE. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:00:26
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49

PRODUCTION RELEASE (v12.003
EAB) (1725)

1243 of 1640

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Lauren Vigil (b) (4) (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:54:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
User entered empty.	System	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:00
User closed query 'Per CDM: Please verify if there is an End Date to this AE, and update form as appropriate per Protocol. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:03:33
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:00:50
Query 'Per CDM: Please verify if there is an End Date to this AE, and update form as appropriate per Protocol. Thank you.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 16:48:56
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 16:48:50
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Feb 2021 16:48:50
User opened query 'Per CDM: Please verify if there is an End Date to this AE, and update form as appropriate per Protocol. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 14:38:48
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 00:41:53
User closed query 'Unable to verify, please provide source so CRA can verify end date. ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 00:41:50
Query 'Unable to verify, please provide source so CRA can verify end date. ' answered with 'Source sent via email.' (Site from CRA).	Lauren Vigil (b) (4) (b) (4)	23 Mar 2021 23:55:06
User opened query 'Unable to verify, please provide source so CRA can verify end date. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 05:17:52
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:00:50
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Feb 2021 16:50:47
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Feb 2021 16:50:47
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Feb 2021 16:50:37
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Feb 2021 16:50:37
User entered '3 Dec 2020' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:50:37
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Feb 2021 16:49:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 16:49:53
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:49:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 16:49:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 16:49:16

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN Jan UNK' (non-conformant).	Lauren Vigil (b) (4)	19 Feb 2021 16:49:16
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 16:48:50
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 16:48:50
	(b) (4)	
User entered 'Un UNK' (non-conformant).	Lauren Vigil (b) (4)	19 Feb 2021 16:48:50
	(b) (4)	
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:17:55
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
User entered empty.	System	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 00:42:06
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:17:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:00
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:02
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:06
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:09
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:11
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:18
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:23
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:53
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:56
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:18:58
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:01
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4) (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:05
User signature succeeded.	Michael Lewis (b) (4)	15 Dec 2020 22:40:44
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 02 Oct 2020 and AE#1 has a start date 19 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:45:35
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 02 Oct 2020 and AE#1 has a start date 19 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	11 Dec 2020 16:21:33
Signature has been broken.	Lauren Vigil (b) (4)	11 Dec 2020 16:21:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	11 Dec 2020 16:21:28
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 02 Oct 2020 and AE#1 has a start date 19 Nov 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 10:32:35
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'None (NONE)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:24
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	03 Dec 2020 22:11:56
User entered '1'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:27
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) term. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:03:38
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) term. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:49:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) term. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:35:34
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:35:10
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:34:15
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '1' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	03 Dec 2020 22:11:56
User entered '0'	Lauren Vigil (b) (4) (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:29
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:31
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:00:50
Signature has been broken.	Lauren Vigil (b) (4)	19 Feb 2021 16:50:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lauren Vigil (b) (4)	19 Feb 2021 16:50:47
Data Entry Error	(b) (4)	
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:33
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:19:45
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'REPORTS STOMACH FLU X 1 WEEK, STARTED 2 WEEKS AGO. STARTED MEDICATIONS IMMIDIUM PRN FOR DIARRHEA AND ONDANSETRON PRN FOR NAUSEA. DENIES FEVER OR CHILLS. PCR NASAL SWAB NEGATIVE ON 12/01'	Lauren Vigil (b) (4)	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
User entered '0'	System	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00
User entered '0'	System	03 Dec 2020 22:09:04

US3882011

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:20:00

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:11:34
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:03
User entered 'USA-US095-2021-mRNA-1273-P301000002'	System	08 Jan 2021 20:37:58
User entered 'New'	(b) (4), (b) (6)	08 Jan 2021 20:37:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:13:08
User closed query 'Per CDM Re-query: AE term on this form indicates underlying cause of death is unknown, however, please consider updating AE term on this form to include new information that has become available (and is recorded on EOS/ Study Discontinuation form). Please note, on EOS/ Study Discontinuation form, 'Reason for Discontinuation' is Death. 'If Reason for Discontinuation is Death, main cause of Death' is Other. 'If main cause of Death is Other, specify' is 'Seizure'. Therefore, if appropriate, please update this AE term to include this new information. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:13:26
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:00:50
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 19:34:27
User coded data point as SOC: Nervous system disorders, HLT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 16:56:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 16:56:52
Data point term sent to Coder	System	19 Feb 2021 16:55:33
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:55:18
User entered 'Seizure' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:55:18

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information please state so.' answered with 'Underlying cause of death is unknown' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:52:59
Query 'Per CDM Re-query: AE term on this form indicates underlying cause of death is unknown, however, please consider updating AE term on this form to include new information that has become available (and is recorded on EOS/ Study Discontinuation form). Please note, on EOS/ Study Discontinuation form, 'Reason for Discontinuation' is Death. 'If Reason for Discontinuation is Death, main cause of Death' is Other. 'If main cause of Death is Other, specify' is 'Seizure'. Therefore, if appropriate, please update this AE term to include this new information. Thank you. ' answered with 'No new information available' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:52:40
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known. Please consider leaving query open until information becomes available. If it is not expected to obtain this information please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:20:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Unknown cause of death - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 18:30:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 18:30:23
Data point term sent to Coder	System	28 Jan 2021 16:14:17
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 16:13:26
User entered 'INDICATES UNDERLYING CAUSE OF DEATH IS UNKNOWN' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 16:13:26

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: AE term on this form indicates underlying cause of death is unknown, however, please consider updating AE term on this form to include new information that has become available (and is recorded on EOS/ Study Discontinuation form). Please note, on EOS/ Study Discontinuation form, 'Reason for Discontinuation' is Death. 'If Reason for Discontinuation is Death, main cause of Death' is Other. 'If main cause of Death is Other, specify' is 'Seizure'. Therefore, if appropriate, please update this AE term to include this new information. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:33:22
Query 'Per CDM Re-query: AE term on this form indicates underlying cause of death is unknown, however, please consider AE updating term to include new information that has become available and is recorded on EOS/ Study Discontinuation form. Please note, on EOS/ Study Discontinuation form, 'Reason for Discontinuation' is Death. 'If Reason for Discontinuation is Death, main cause of Death' is Other. 'If main cause of Death is Other, specify' is 'Seizure'. Therefore, if appropriate, please update this AE term to include this new information. Thank you.'	(b) (4), (b) (6)	26 Jan 2021 15:32:20
canceled (Site from DM).		
User opened query 'Per CDM Re-query: AE term on this form indicates underlying cause of death is unknown, however, please consider AE updating term to include new information that has become available and is recorded on EOS/ Study Discontinuation form. Please note, on EOS/ Study Discontinuation form, 'Reason for Discontinuation' is Death. 'If Reason for Discontinuation is Death, main cause of Death' is Other. 'If main cause of Death is Other, specify' is 'Seizure'. Therefore, if appropriate, please update this AE term to include this new information. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:32:03
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 16:03:14

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Unknown cause of death - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 10:56:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 10:56:08
Data point term sent to Coder	System	15 Jan 2021 19:46:39
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known.' answered with 'Underlying cause of death is unknown' (Site from Safety).	Lauren Vigil (b) (4)	15 Jan 2021 19:46:09
Coding entries removed.	Lauren Vigil (b) (4)	15 Jan 2021 19:46:05
Signature has been broken.	Lauren Vigil (b) (4)	15 Jan 2021 19:46:05
User entered 'DEATH; Underlying cause of death is unknown' reason for change: Data Entry Error	Lauren Vigil (b) (4)	15 Jan 2021 19:46:05
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death, if known.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:33:45
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Death - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 03:14:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Jan 2021 03:14:35
Data point term sent to Coder	System	08 Jan 2021 03:14:15
User entered 'Death'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:13:12
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:13:16
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:16:01
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:16:05
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:16:07
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
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	08 Jan 2021 03:14:17
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	08 Jan 2021 03:14:17
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	08 Jan 2021 03:13:58
User entered '18:50'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
User entered empty.	System	08 Jan 2021 03:14:17
User entered '6 Jan 2021 18:50'	System	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:16:10
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'No (N)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:16:14
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:23
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered empty.	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
User entered empty.	System	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:19
User closed query 'Per DM CLR: AE resulted in Death. However, CTCAE is not grade 5. Please review death details and reconcile as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 11:45:03
Query 'Per DM CLR: AE resulted in Death. However, CTCAE is not grade 5. Please review death details and reconcile as appropriate. Otherwise, provide clarification.' answered with 'Grade 5 not an option' (Site from DM).	Lauren Vigil (b) (4)	01 Mar 2021 16:58:44
User opened query 'Per DM CLR: AE resulted in Death. However, CTCAE is not grade 5. Please review death details and reconcile as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4)	26 Feb 2021 15:01:05
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Grade 4 (Grade 4)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:15
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:31
User closed query 'PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 19:34:36
Query 'PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information please state so. ' answered with 'No further information available' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:53:28
User opened query 'PV Query: Please provide/confirm the cause of death, please consider leaving query open until information becomes available. If it is not expected to obtain this information please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:21:07
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'I'	Lauren Vigil (b) (4) (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:34
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '0'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:37
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)	19 Feb 2021 19:34:40
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 'unable to retain records' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:53:16
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)	25 Jan 2021 21:01:32
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '0'	Lauren Vigil (b) (4) (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:40
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered empty.	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:42
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered empty.	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:46
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered empty.	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:48
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered empty.	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:50
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '0'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:52
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '0'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:55
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '0'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:14:57
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4) (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:15:00
Query 'Per CDM: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Please verify if subject received the study drug. If no, this should be not applicable. If yes, this should be Related or Not Related. Please confirm correct or update accordingly. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:43:50
User opened query 'Per CDM: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Please verify if subject received the study drug. If no, this should be not applicable. If yes, this should be Related or Not Related. Please confirm correct or update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:42:59
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Not Related (NOT RELATED)'	Lauren Vigil (b) (4) (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:15:03
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:00:50
User closed query 'PV Query: As the last dose of study drug was given on [02 Oct 2020] prior to SAE, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 16:03:18
Query 'PV Query: As the last dose of study drug was given on [02 Oct 2020] prior to SAE, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Lauren Vigil (b) (4)	15 Jan 2021 19:46:15
Signature has been broken.	Lauren Vigil (b) (4)	15 Jan 2021 19:46:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	15 Jan 2021 19:46:05
User opened query 'PV Query: As the last dose of study drug was given on [02 Oct 2020] prior to SAE, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:32:59
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'None (NONE)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:15:29
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'l'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:15:26
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '0'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:15:23
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '0'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58
	(b) (4)	

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:15:21
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Fatal (FATAL)'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:15:31
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered empty.	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
User closed query 'PV Query: Please send emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:54:29
Query 'PV Query: Please send emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' answered with 'Supporting documents sent via email to Safety_moderna@iqvia.com' (Site from Safety).	Justine Velandria (b) (4) (b) (4)	26 Apr 2021 19:03:10
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:16:30
User opened query 'PV Query: Please send emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:58:09
User closed query 'PV Query: Please send a emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent. If records will not be able to be obtained at any time in the future, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:27:00

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent. If records will not be able to be obtained at any time in the future, please state so in your response.' answered with 'We must address every query for the database lock. At this time records will not be obtained in the near future' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	02 Mar 2021 19:44:21
User opened query 'PV Query: Please send a emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent. If records will not be able to be obtained at any time in the future, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 18:16:41
User closed query 'PV Query: Please send a emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:41:18
Query 'PV Query: Please send a emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'unable to obtain at present' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	01 Mar 2021 16:59:03
User opened query 'PV Query: Please send a emergency room notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:24:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

1312 of 1640

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide emergency room notes' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 19:34:45
Query 'PV Query: Please provide emergency room notes' answered with 'Emergency room notes are not available' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:53:50
User opened query 'PV Query: Please provide emergency room notes' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:17:22
User closed query 'PV Query: Thank you for your response. Please confirm if underlying cause of death will ever be available. ' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:04:51
User closed query 'PV Query: Thank you for your response. Please confirm if cause of death will ever be available. ' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:04:46
Query 'PV Query: Thank you for your response. Please confirm if cause of death will ever be available. ' answered with 'will update when cause of death is known' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 16:14:02
Query 'PV Query: Thank you for your response. Please confirm if underlying cause of death will ever be available. ' answered with 'Will update when cause of death is known.' (Site from Safety).	Lauren Vigil (b) (4) (b) (4)	28 Jan 2021 16:13:52
User opened query 'PV Query: Thank you for your response. Please confirm if underlying cause of death will ever be available. ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:01:19
User opened query 'PV Query: Thank you for your response. Please confirm if cause of death will ever be available. ' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 21:00:30
User closed query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 16:03:25
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 16:03:23
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided or unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 16:03:20

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided or unknown, please state so.' answered with 'acknowledged' (Site from Safety).	Lauren Vigil (b) (4)	15 Jan 2021 19:46:51
Query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so.' answered with 'It is not known if an autopsy was performed' (Site from Safety).	Lauren Vigil (b) (4)	15 Jan 2021 19:46:37
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Underlying cause of death is unknown' (Site from Safety).	Lauren Vigil (b) (4)	15 Jan 2021 19:46:20
User opened query 'PV Query: Please provide autopsy results if performed. If not performed or unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:33:53
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:33:36
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided or unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:33:06
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Subject (b) (6) At (b) (6) was notified that subject was experiencing chest pain 10/10 radiating to shoulder blades. EMTs were called and they performed EKG with normal sinus rhythm. As the subject attempted to sit up they went into a seizure. EMTs transported subject to ER where the subject passed away'	Lauren Vigil (b) (4)	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
User entered '1'	System	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46
User entered '1'	System	08 Jan 2021 03:13:58

US3882011

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:50:46

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:58:11
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
Signature has been broken.	Lauren Vigil (b) (4)	22 Sep 2020 17:19:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	22 Sep 2020 17:19:44
User signature succeeded.	Michael Lewis (b) (4)	19 Sep 2020 00:32:20
User entered 'No (N)'	Lauren Vigil (b) (4)	17 Sep 2020 19:10:36

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 01:32:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 01:32:55
Data point term sent to Coder	System	21 Nov 2020 01:31:50
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	21 Nov 2020 01:31:26
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:21:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:21:49
Data point term sent to Coder	System	22 Sep 2020 17:21:01
User entered 'Acetaminophen'	Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:08
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Signature has been broken.	Justine Velandria (b) (4)	17 Feb 2021 21:44:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Justine Velandria (b) (4)	17 Feb 2021 21:44:24
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:19
User closed query 'Per CDM RQ : Data is Not updated, please review and update. Thank You' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:32:54
Query 'Per CDM RQ : Data is Not updated, please review and update. Thank You' answered with 'Unable to update further. The subject has passed away' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Feb 2021 16:51:44
User opened query 'Per CDM RQ : Data is Not updated, please review and update. Thank You' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:59:28
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:59:28
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Justine Velandria (b) (4) (b) (4)	17 Feb 2021 21:45:32
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:11:36
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE 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)	24 Nov 2020 11:01:03

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM). Signature has been broken.	Lauren Vigil (b) (4) (b) (4)	21 Nov 2020 01:31:32
	Lauren Vigil (b) (4) (b) (4)	21 Nov 2020 01:31:26
User entered 'general body PAIN' reason for change: Data Entry Error	Lauren Vigil (b) (4) (b) (4)	21 Nov 2020 01:31:26
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE 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) (b) (4)	18 Nov 2020 04:17:47
User signature succeeded.	Michael Lewis (b) (4) (b) (4)	23 Sep 2020 23:44:05
User entered 'Pain'	Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:23
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '500'	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:27
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mg (mg)'	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:45
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:47
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'four times daily (QID)'	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:50
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:54
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:43:56
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:00
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:03
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'l'	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:05
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:06
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:09
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 17:20:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 17:20:56
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	22 Sep 2020 17:20:56
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 17:20:47
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '4'	System	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:20:47

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:31
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: COLECALCIFEROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 21:48:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 21:48:16
Data point term sent to Coder	System	17 Feb 2021 21:47:30
Coding entries removed.	Justine Velandria (b) (4)	17 Feb 2021 21:46:45
Signature has been broken.	(b) (4) Justine Velandria (b) (4)	17 Feb 2021 21:46:45
User entered 'cholecalciferol' reason for change:	Justine Velandria (b) (4)	17 Feb 2021 21:46:45
Data Entry Error	(b) (4)	
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 22:24:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 22:24:51
Data point term sent to Coder	System	22 Sep 2020 17:22:03
User entered 'Cholecalcif'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:34
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:01:07
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	21 Nov 2020 01:31:48
Signature has been broken.	Lauren Vigil (b) (4)	21 Nov 2020 01:31:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	21 Nov 2020 01:31:43
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:18:06
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:37
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
User closed query 'Per CDM: Site reports 'Cholecalcif' is taken as a supplement, and Prophylaxis = YES. Please consider updating 'Indication' field to "Prophylaxis for Health Promotion" if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:00:09
Query 'Per CDM: Site reports 'Cholecalcif' is taken as a supplement, and Prophylaxis = YES. Please consider updating 'Indication' field to "Prophylaxis for Health Promotion" if appropriate. Thank you.' answered with 'updated' (Site from DM).	Justine Velandria (b) (4)	17 Feb 2021 21:47:06
Signature has been broken.	Justine Velandria (b) (4)	17 Feb 2021 21:47:01
User entered 'Prophylaxis for Health Promotion' reason for change: Data Entry Error	Justine Velandria (b) (4)	17 Feb 2021 21:47:01
User opened query 'Per CDM: Site reports 'Cholecalcif' is taken as a supplement, and Prophylaxis = YES. Please consider updating 'Indication' field to "Prophylaxis for Health Promotion" if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 14:47:44
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Supplementation'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:40
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '25'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:44:51
User signature succeeded.	Michael Lewis (b) (4)	06 Oct 2020 00:39:45
Signature has been broken.	Lauren Vigil (b) (4)	05 Oct 2020 20:18:47
User entered 'ug (ug)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	05 Oct 2020 20:18:47
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Other (OTHER)'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:12
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is can be one of the available option 'ug ' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:27:48
User signature succeeded.	Michael Lewis (b) (4)	06 Oct 2020 00:39:45
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is can be one of the available option 'ug ' from the drop down list. Please update accordingly. Else Clarify.' answered with 'Form has been updated' (Site from DM).	Lauren Vigil (b) (4)	05 Oct 2020 20:18:51
Signature has been broken.	Lauren Vigil (b) (4)	05 Oct 2020 20:18:47
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	05 Oct 2020 20:18:47
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is can be one of the available option 'ug ' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:55:46
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'MCG'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:15
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:17
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:19
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:21
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:24
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:26
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'l'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:30
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:37
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:38
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:21:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:45:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: DULOXETINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:08:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:08:05
Data point term sent to Coder	System	23 Nov 2020 19:41:40
Coding entries removed.	Lauren Vigil (b) (4)	23 Nov 2020 19:41:20
User closed query 'Per MM, Please recode to N06AX' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:35:03
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: DULOXETINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:34:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:34:31
Query 'Per MM, Please recode to N06AX' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	19 Oct 2020 16:00:40
Data point term sent to Coder	System	19 Oct 2020 16:00:38
Coding entries removed.	Lauren Vigil (b) (4)	19 Oct 2020 16:00:34
Signature has been broken.	(b) (4) Lauren Vigil (b) (4)	19 Oct 2020 16:00:34
User entered 'DULOXETINE HCL N06AX' reason for change: Data Entry Error	(b) (4)	19 Oct 2020 16:00:34
User opened query 'Per MM, Please recode to N06AX' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:33:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: DULOXETINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 23:11:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 23:11:46
Data point term sent to Coder	System	22 Sep 2020 17:24:05
User entered 'Duloxetine HCL'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:00
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:06
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 15:06:18
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Reconciled with Med History eCRF' (Site from DM).	Lauren Vigil (b) (4)	23 Nov 2020 19:41:24
Signature has been broken.	Lauren Vigil (b) (4)	23 Nov 2020 19:41:20
User entered 'MOOD - DEPRESSION' reason for change: Data Entry Error	Lauren Vigil (b) (4)	23 Nov 2020 19:41:20
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:18:33
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mood'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:12
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '30'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:14
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mg (mg)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:16
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:19
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:21
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:23
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:24
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:26
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:28
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'l'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:30
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:32
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:34
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:23:18

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:43
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:20:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 23:20:45
Data point term sent to Coder	System	22 Sep 2020 17:24:06
User entered 'Fish oil'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:45
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:01:11
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	21 Nov 2020 01:32:08
Signature has been broken.	Lauren Vigil (b) (4)	21 Nov 2020 01:32:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	21 Nov 2020 01:32:02
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:18:49
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:48
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'supplementation'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:50
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '1000'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:52
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mg (mg)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:54
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:56
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:46:57
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:00
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:04
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:07
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:09
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'I'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:12
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:14
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:17
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:23:57

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:33
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROXYZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:25:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:25:47
Data point term sent to Coder	System	22 Sep 2020 17:25:07
User entered 'Hydroxyzine HCL'	Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:36
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:38
User closed query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:19:17
Query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Reconciled with Med History eCRF' (Site from DM).	Lauren Vigil (b) (4) (b) (4)	23 Nov 2020 19:41:47
User opened query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:19:41
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'anxiety'	Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:41
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '25'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:43
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mg (mg)'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:45
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:50
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'three times daily (TID)'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:52
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:54
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:56
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:47:58
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:00
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'I'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:03
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:05
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:07
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '3'	System	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:24:44

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:24
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)	21 Nov 2020 01:33:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 01:33:56
Data point term sent to Coder Coding entries removed.	System Lauren Vigil (b) (4) (b) (4)	21 Nov 2020 01:32:51 21 Nov 2020 01:32:23
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
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)	22 Sep 2020 17:27:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:27:45
Data point term sent to Coder User entered 'Ibuprofen'	System Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:26:08 22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:26
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:31
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE 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)	24 Nov 2020 11:01:17
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	21 Nov 2020 01:32:28
Signature has been broken.	Lauren Vigil (b) (4)	21 Nov 2020 01:32:23
User entered 'general body PAIN' reason for change: Data Entry Error	Lauren Vigil (b) (4)	21 Nov 2020 01:32:23
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Review and update medical history/AE 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)	18 Nov 2020 04:20:09
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'pain'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:33
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '600'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:36
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mg (mg)'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:40
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:42
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'three times daily (TID)'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:47
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:50
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:54
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:48:57
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:00
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'I'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:02
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:06
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:08
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '3'	System	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:25:16

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOTHYROXINE NA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:21:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:21:21
Data point term sent to Coder	System	13 Oct 2020 15:20:25
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	13 Oct 2020 15:19:30
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOTHYROXINE NA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:27:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:27:45
Data point term sent to Coder	System	22 Sep 2020 17:26:09
User entered 'Levothyroxine NA'	Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:28
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:30
User signature succeeded.	Michael Lewis (b) (4)	15 Oct 2020 01:26:57
User closed query 'Per CDM: Indication is recorded as "Thyroid". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Hyperthyroidism).' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 11:11:16
Query 'Per CDM: Indication is recorded as "Thyroid". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Hyperthyroidism).' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	13 Oct 2020 15:19:37
Signature has been broken.	Lauren Vigil (b) (4)	13 Oct 2020 15:19:30
User entered 'THYROID/Hypothyroidism' reason for change: Data Entry Error	Lauren Vigil (b) (4)	13 Oct 2020 15:19:30
User opened query 'Per CDM: Indication is recorded as "Thyroid". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Hyperthyroidism).' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:23:59
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Thyroid'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:33
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '200'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:35
User signature succeeded.	Michael Lewis (b) (4)	06 Oct 2020 00:39:45
Signature has been broken.	Lauren Vigil (b) (4)	05 Oct 2020 20:19:36
User entered 'ug (ug)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	05 Oct 2020 20:19:36
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Other (OTHER)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:38
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is can be one of the available option 'ug ' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:27:53
User signature succeeded.	Michael Lewis (b) (4)	06 Oct 2020 00:39:45
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is can be one of the available option 'ug ' from the drop down list. Please update accordingly. Else Clarify.' answered with 'Form has been updated' (Site from DM).	Lauren Vigil (b) (4)	05 Oct 2020 20:19:41
Signature has been broken.	Lauren Vigil (b) (4)	05 Oct 2020 20:19:36
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	05 Oct 2020 20:19:36
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is can be one of the available option 'ug ' from the drop down list. Please update accordingly. Else Clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:36:35
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'MCG'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:42
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:45
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:49
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:51
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:53
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:56
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'l'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:49:58
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:50:01
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:50:04
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:26:02

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:50:49
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)	23 Nov 2020 20:15:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:15:18
Data point term sent to Coder Coding entries removed.	System Lauren Vigil (b) (4) (b) (4)	23 Nov 2020 19:42:41 23 Nov 2020 19:42:15
User signature succeeded.	Michael Lewis (b) (4) (b) (4)	23 Sep 2020 23:44:05
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)	22 Sep 2020 17:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:27:46
Data point term sent to Coder User entered 'Lisinopril'	System Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:27:10 22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:32
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:50:53
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 10:59:52
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Reconciled with Med History eCRF' (Site from DM).	Lauren Vigil (b) (4)	23 Nov 2020 19:42:19
Signature has been broken.	Lauren Vigil (b) (4)	23 Nov 2020 19:42:15
User entered 'high BLOOD PRESSURE' reason for change: Data Entry Error	Lauren Vigil (b) (4)	23 Nov 2020 19:42:15
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:23:38
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Blood Pressure'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:50:55
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '20'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:50:57
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mg (mg)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:50:59
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:02
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:04
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:06
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:08
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:11
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:13
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'l'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:15
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:17
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:20
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:26:51

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:47
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.	Coder Import (b) (4) (b) (4)	26 Nov 2020 08:30:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Nov 2020 08:30:07
Data point term sent to Coder	System	26 Nov 2020 01:37:59
Datapoint queued for coding (5163923).	System	26 Nov 2020 01:37:42
Data point term sent to Coder	System	23 Nov 2020 19:42:41
Coding entries removed.	Lauren Vigil (b) (4) (b) (4)	23 Nov 2020 19:42:32
User signature succeeded.	Michael Lewis (b) (4) (b) (4)	23 Sep 2020 23:44:05
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.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:28:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 17:28:47
Data point term sent to Coder	System	22 Sep 2020 17:28:11
User entered 'Simvastatin'	Lauren Vigil (b) (4) (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:49
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:52
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 13:37:19
User signature succeeded.	Michael Lewis (b) (4)	26 Nov 2020 18:49:24
User entered 'HIGH CHOLESTEROL (HYPERLIPIDEMIA)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	23 Nov 2020 19:43:42
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Reconciled with Med History eCRF' (Site from DM).	Lauren Vigil (b) (4)	23 Nov 2020 19:42:38
Signature has been broken.	Lauren Vigil (b) (4)	23 Nov 2020 19:42:32
User entered 'HIGH CHOLESTEROL' reason for change: Data Entry Error	Lauren Vigil (b) (4)	23 Nov 2020 19:42:32
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 04:24:21
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'cholesterol'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:55
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered '20'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:51:58
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'mg (mg)'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:01
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:03
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'once daily (QD)'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:05
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:15
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:12
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:07
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:19
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:21
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:23
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'l'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:25
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:28
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered empty.	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:30
User signature succeeded.	Michael Lewis (b) (4)	23 Sep 2020 23:44:05
User entered 'No (N)'	Lauren Vigil (b) (4)	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	22 Sep 2020 17:27:25

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:52:55
User closed query 'Per DM CLR: Con Med VARENICILINewas added/changed on 17 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition TOBACCO USER requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:02:09
Query 'Per DM CLR: Con Med VARENICILINewas Justine Velandria added/changed on 17 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition TOBACCO USER requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'con med was added related to a change in lifestyle, not worsening/exacerbation of condition' (Site from DM).	(b) (4) (b) (4)	17 Feb 2021 21:48:48
User opened query 'Per DM CLR: Con Med VARENICILINewas added/changed on 17 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition TOBACCO USER requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:12:20
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:07:35

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'VARENICILINE'	Coder Import (b) (4) (b) (4) System Lauren Vigil (b) (4) (b) (4)	27 Oct 2020 05:07:35 26 Oct 2020 19:40:48 26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:12
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:40:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:40:40
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	26 Oct 2020 19:40:40
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:40:33
User entered empty.	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:14
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'SMOKING CESSATION'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:17
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'l'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:20
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'mg (mg)'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:26
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered empty.	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:23
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'twice daily (BID)'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:38
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered empty.	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:35
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:33
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered empty.	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:30
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '17 Oct 2020'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:40
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered '0'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:42
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered 'Yes (Y)'	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:44
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User entered empty.	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:53:46
User signature succeeded.	Michael Lewis (b) (4)	30 Oct 2020 01:10:11
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:40:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:40:44
User entered 'No (N)' reason for change: Data Entry Error	Lauren Vigil (b) (4)	26 Oct 2020 19:40:44
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:40:33
User entered empty.	Lauren Vigil (b) (4)	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '2'	System	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '1'	System	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered '804 (804)'	System	26 Oct 2020 19:40:33

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:54:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:10:45
Data point term sent to Coder	System	17 Feb 2021 21:49:32
Coding entries removed.	Justine Velandria (b) (4) (b) (4)	17 Feb 2021 21:49:23
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:40:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:40:02
Data point term sent to Coder	System	03 Dec 2020 19:38:59
User entered 'LOPERAMIDE'	Lauren Vigil (b) (4) (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:54:17
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:54:38
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
User closed query 'Per CDM: Per 'Narrative' on AE Log Line 1 (Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:04:03
Query 'Per CDM: Per 'Narrative' on AE Log Line 1 (Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' answered with 'updated' (Site from DM).	Justine Velandria (b) (4)	17 Feb 2021 21:49:29
Signature has been broken.	Justine Velandria (b) (4)	17 Feb 2021 21:49:23
User entered 'stomach flu with DIARRHEA' reason for change: Data Entry Error	Justine Velandria (b) (4)	17 Feb 2021 21:49:23
User opened query 'Per CDM: Per 'Narrative' on AE Log Line 1 (Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:07:37
Query 'Per CDM: Per 'Narrative' on AE Log Line 1(Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:07:12
User opened query 'Per CDM: Per 'Narrative' on AE Log Line 1(Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:07:04

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' canceled (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 04:09:54
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.	(b) (4), (b) (6)	26 Jan 2021 04:09:52
' (Site from DM).		
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'DIARRHEA'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:26
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '2'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:29
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'mg (mg)'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:32
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:34
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'as needed (PRN)'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:36
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:38
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:55:40
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
DataPoint Verified.	(b) (4), (b) (6)	20 Mar 2021 20:55:43
User closed query 'Start date on source notes medication was started on 16Nov2020. Please reconcile and update as needed. ' (Site from CRA). Query 'Start date on source notes medication was started on 16Nov2020. Please reconcile and update as needed. ' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6)	20 Mar 2021 20:55:07
Signature has been broken.	Lauren Vigil (b) (4)	19 Mar 2021 16:56:01
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 16:55:30
User opened query 'Start date on source notes medication was started on 16Nov2020. Please reconcile and update as needed. ' (Site from CRA).	Lauren Vigil (b) (4)	19 Mar 2021 16:55:30
User signature succeeded.	(b) (4)	19 Mar 2021 04:56:48
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:04:15
Signature has been broken.	Justine Velandria (b) (4)	17 Feb 2021 21:59:34
User entered empty; reason for change Data Entry Error	(b) (4)	17 Feb 2021 21:59:28
	Justine Velandria (b) (4)	17 Feb 2021 21:59:28

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. 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)	26 Jan 2021 04:10:14
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '16 Nov 2020'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:28:19
User signature succeeded.	Michael Lewis (b) (4)	20 Mar 2021 23:10:53
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	19 Mar 2021 16:56:14
Signature has been broken.	Lauren Vigil (b) (4)	19 Mar 2021 16:56:14
User entered '0' reason for change: Data Entry Error	Lauren Vigil (b) (4)	19 Mar 2021 16:56:14
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	19 Mar 2021 16:55:30
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Signature has been broken.	Justine Velandria (b) (4)	17 Feb 2021 21:59:28
User entered '1' reason for change: Data Entry Error	Justine Velandria (b) (4)	17 Feb 2021 21:59:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:28:35
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:38
User closed query 'Source does not note an END DATE. Please reconcile and update as needed and/or provide updated source for verification. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:15:36
Query 'Source does not note an END DATE. Please reconcile and update as needed and/or provide updated source for verification. ' answered with 'Source updated. ' (Site from CRA).	Lauren Vigil (b) (4) (b) (4)	19 Mar 2021 16:56:31
User opened query 'Source does not note an END DATE. Please reconcile and update as needed and/or provide updated source for verification. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 05:04:11
Query 'Source does not note an END DATE. Please reconcile and update as needed. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 05:03:36
User opened query 'Source does not note an END DATE. Please reconcile and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 04:57:27
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '03 Dec 2020'	Lauren Vigil (b) (4) (b) (4)	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:03:05
Query 'Please confirm if this medication was taken for the flu which also started on 16Nov2020? ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 05:03:03
User opened query 'Please confirm if this medication was taken for the flu which also started on 16Nov2020? ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 04:59:04
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 19:38:38
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	03 Dec 2020 19:38:38

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:59:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 10:55:01
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 Feb 2021 10:55:01
Data point term sent to Coder	System	17 Feb 2021 21:50:33
Coding entries removed.	Justine Velandria (b) (4) (b) (4)	17 Feb 2021 21:49:39
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:41:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:41:00
Data point term sent to Coder	System	03 Dec 2020 19:40:00
User entered 'ONDANSETRON'	Lauren Vigil (b) (4) (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:59:21
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:59:24
User closed query 'Per CDM RQ : Please review this event was not updated in AE eCRF. so please review and updated. Thank You' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:33:06
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Query 'Per CDM RQ : Please review this event was not updated in AE eCRF. so please review and updated. Thank You' answered with 'updated' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 16:52:02
User opened query 'Per CDM RQ : Please review this event was not updated in AE eCRF. so please review and updated. Thank You' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:09:29
User closed query 'Per CDM: Per 'Narrative' on AE Log Line 1 (Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 12:09:29
Query 'Per CDM: Per 'Narrative' on AE Log Line 1 (Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' answered with 'updated' (Site from DM).	Justine Velandria (b) (4)	17 Feb 2021 21:49:44
Signature has been broken.	Justine Velandria (b) (4)	17 Feb 2021 21:49:39
User entered 'stomach flu with NAUSEA' reason for change: Data Entry Error	Justine Velandria (b) (4)	17 Feb 2021 21:49:39
User opened query 'Per CDM: Per 'Narrative' on AE Log Line 1 (Stomach Flu), site reports subject received Imodium (Loperamide) for Diarrhea, and Ondansetron for Nausea. Kindly update Indication field on this form as appropriate to reconcile with AE form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 15:08:28
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'NAUSEA'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:59:32
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '4'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 04:59:45
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'mg (mg)'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:31
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:35
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'as needed (PRN)'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:38
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:40
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'Oral (ORAL)'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:50
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered empty.	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:52
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '16 Nov 2020'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:54
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '0'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:30:37
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 05:05:08
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:04:57
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31
	(b) (4)	

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:15:50
User closed query 'The source provided to CRA for verification does not have an END DATE. Please clarify? ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:15:48
Query 'The source provided to CRA for verification does not have an END DATE. Please clarify? ' answered with 'Source updated.' (Site from CRA).	Lauren Vigil (b) (4)	19 Mar 2021 16:58:47
User opened query 'The source provided to CRA for verification does not have an END DATE. Please clarify? ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 05:05:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 05:05:06
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:05:01
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered '03 Dec 2020'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:05:10
User signature succeeded.	Michael Lewis (b) (4)	07 Dec 2020 01:39:49
User entered 'No (N)'	Lauren Vigil (b) (4)	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User entered empty.	System	03 Dec 2020 19:39:31

US3882011

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:16:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 01:26:00
User closed query 'Per Narrative EKG was performed, procedure not present in Concomitant procedures, please update. ' (Site from CRA).	(b) (4), (b) (6)	30 Jan 2021 01:25:58
Query 'Per Narrative EKG was performed, procedure not present in Concomitant procedures, please update. ' answered with 'updated' (Site from CRA).	Lauren Vigil (b) (4)	28 Jan 2021 16:12:01
Signature has been broken.	(b) (4)	
	Lauren Vigil (b) (4)	28 Jan 2021 16:09:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lauren Vigil (b) (4)	28 Jan 2021 16:09:00
User opened query 'Per Narrative EKG was performed, procedure not present in Concomitant procedures, please update. ' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	28 Jan 2021 00:58:55
	Michael Lewis (b) (4)	19 Sep 2020 00:32:20
User entered 'No (N)'	(b) (4)	
	Lauren Vigil (b) (4)	17 Sep 2020 19:10:43
	(b) (4)	

US3882011

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:07:01
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	28 Jan 2021 16:11:54

US3882011

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 01:27:21
User entered 'EKG'	Lauren Vigil (b) (4)	28 Jan 2021 16:11:54
	(b) (4)	

US3882011

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 01:27:37
User entered 'Adverse Event (AE)'	Lauren Vigil (b) (4)	28 Jan 2021 16:11:54

US3882011

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 01:27:39
User entered empty.	Lauren Vigil (b) (4)	28 Jan 2021 16:11:54
	(b) (4)	

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:50:45
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	08 Jan 2021 03:16:32
User entered '6 Jan 2021' reason for change: Data Entry Error	Lauren Vigil (b) (4)	08 Jan 2021 03:16:32
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	(b) (4)	08 Jan 2021 03:15:56
User entered '7 Jan 2021'	Lauren Vigil (b) (4)	08 Jan 2021 03:15:56
	(b) (4)	

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:50:47
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Death (DEATH)'	Lauren Vigil (b) (4)	08 Jan 2021 03:15:56

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:50:48
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	08 Jan 2021 03:16:32
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	08 Jan 2021 03:16:32
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	08 Jan 2021 03:15:56
User entered 'Death'	Lauren Vigil (b) (4)	08 Jan 2021 03:15:56

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User closed query 'Per CDM: Seizure' is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 20:32:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:04:59
User signature succeeded.	Michael Lewis (b) (4)	19 Apr 2021 21:13:23
Query 'Per CDM: Seizure' is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.'	Lauren Vigil (b) (4)	19 Apr 2021 16:59:20
answered with 'updated' (Site from DM).	(b) (4)	
User closed query 'Main cause of death is not Other, System however specify is provided. Please correct.' (Site from System).	System	19 Apr 2021 16:59:04
User opened query 'Main cause of death is not Other, System however specify is provided. Please correct.' (Site from System).	System	19 Apr 2021 16:58:36
DataPoint Un-verified.	Lauren Vigil (b) (4)	19 Apr 2021 16:58:36
Signature has been broken.	(b) (4)	
	Lauren Vigil (b) (4)	19 Apr 2021 16:58:36
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Seizure' is listed as an AE with outcome of death, therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:20:05
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:51:02
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Other (OTHER)'	Lauren Vigil (b) (4)	08 Jan 2021 03:15:56
	(b) (4)	

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 03:05:02
User signature succeeded.	Michael Lewis (b) (4)	19 Apr 2021 21:13:23
DataPoint Un-verified.	Lauren Vigil (b) (4)	19 Apr 2021 16:59:04
Signature has been broken.	Lauren Vigil (b) (4)	19 Apr 2021 16:59:04
User entered empty; reason for change Data Entry Error	Lauren Vigil (b) (4)	19 Apr 2021 16:59:04
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:51:05
User closed query 'Per CDM: Please verify and ensure data is recorded in appropriate field on this form. If you are reporting main cause of death is Seizure, please consider recording 'Seizure' under, "If reason for discontinuation is Death, main cause of death" field. If death was caused by an adverse event, the same adverse event must be recorded in the adverse event section as per page 52 of v4.0 of CCGs. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:33:27
Query 'Per CDM: Please verify and ensure data is recorded in appropriate field on this form. If you are reporting main cause of death is Seizure, please consider recording 'Seizure' under, "If reason for discontinuation is Death, main cause of death" field. If death was caused by an adverse event, the same adverse event must be recorded in the adverse event section as per page 52 of v4.0 of CCGs. Thank you.' answered with 'main cause of death is recorded as seizure' (Site from DM).	Lauren Vigil (b) (4)	19 Feb 2021 16:54:48
User opened query 'Per CDM: Please verify and ensure data is recorded in appropriate field on this form. If you are reporting main cause of death is Seizure, please consider recording 'Seizure' under, "If reason for discontinuation is Death, main cause of death" field. If death was caused by an adverse event, the same adverse event must be recorded in the adverse event section as per page 52 of v4.0 of CCGs. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:50:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

1549 of 1640

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

If main cause of death is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Seizure'	Lauren Vigil (b) (4)	08 Jan 2021 03:15:56

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:50:43
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '6 Jan 2021'	Lauren Vigil (b) (4)	08 Jan 2021 03:15:56

US3882011

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 23:51:11
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'Unknown (UNK)'	Lauren Vigil (b) (4)	08 Jan 2021 03:15:56

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:44
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'USA-US095-2021-MRNA-1273-P301000002'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:47
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:55
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:02
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:09
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:12
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:17
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:20
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:32
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Michael'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:38
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Lewis'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:09:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:03:51
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'US'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Signature has been broken.	System	19 Feb 2021 19:38:24
User entered '4'	System	19 Feb 2021 19:38:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '3'	System	29 Jan 2021 15:36:11
Signature has been broken.	System	19 Jan 2021 16:04:04
User entered '2'	System	19 Jan 2021 16:04:04
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '1'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:44
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'USA-US095-2021-MRNA-1273-P301000002'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:47
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:55
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:02
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:09
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:12
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:17
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:20
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:32
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Michael'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:38
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Lewis'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:09:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:03:51
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'US'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Signature has been broken.	System	19 Feb 2021 19:38:24
User entered '4'	System	19 Feb 2021 19:38:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '3'	System	29 Jan 2021 15:36:11
Signature has been broken.	System	19 Jan 2021 16:04:04
User entered '2'	System	19 Jan 2021 16:04:04
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '1'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:56
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '08/Jan/2021 20:38'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:57
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:03:51
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:44
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'USA-US095-2021-MRNA-1273-P301000002'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:47
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:55
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:02
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:09
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:12
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:17
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:20
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:32
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Michael'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:38
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Lewis'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:09:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:03:51
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'US'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Signature has been broken.	System	19 Feb 2021 19:38:24
User entered '4'	System	19 Feb 2021 19:38:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '3'	System	29 Jan 2021 15:36:11
Signature has been broken.	System	19 Jan 2021 16:04:04
User entered '2'	System	19 Jan 2021 16:04:04
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '1'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:11:03
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '19/Jan/2021 16:04'	System	19 Jan 2021 16:04:04

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:11:05
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 19:35:49
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 16:04:04

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:44
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'USA-US095-2021-MRNA-1273-P301000002'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:47
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:55
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:02
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:09
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:12
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:17
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:20
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:32
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Michael'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:38
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Lewis'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:09:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:03:51
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'US'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Signature has been broken.	System	19 Feb 2021 19:38:24
User entered '4'	System	19 Feb 2021 19:38:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '3'	System	29 Jan 2021 15:36:11
Signature has been broken.	System	19 Jan 2021 16:04:04
User entered '2'	System	19 Jan 2021 16:04:04
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '1'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:11:10
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '29/Jan/2021 10:36'	System	29 Jan 2021 15:36:11

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:11:11
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 19:35:49
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 15:36:11

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:44
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'USA-US095-2021-MRNA-1273-P301000002'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:47
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:08:55
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Yes (Y)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:02
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:09
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:12
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:17
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:20
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'No (N)'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:32
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Michael'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:10:38
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 20:38:22
User entered 'Lewis'	System	08 Jan 2021 20:37:58

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 22:03:48

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:09:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 16:03:51
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered 'US'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
Signature has been broken.	System	19 Feb 2021 19:38:24
User entered '4'	System	19 Feb 2021 19:38:24
User signature succeeded.	Michael Lewis (b) (4)	08 Feb 2021 02:44:38
User entered '3'	System	29 Jan 2021 15:36:11
Signature has been broken.	System	19 Jan 2021 16:04:04
User entered '2'	System	19 Jan 2021 16:04:04
User signature succeeded.	Michael Lewis (b) (4)	11 Jan 2021 03:08:41
User entered '1'	System	08 Jan 2021 20:38:30

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:11:16
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
User entered '19/Feb/2021 14:38'	System	19 Feb 2021 19:38:24

US3882011

Folder: SAE USA-US095-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 22:03:48
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 05:11:18
User signature succeeded.	Michael Lewis (b) (4)	21 Feb 2021 20:01:37
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 19:38:24