

US3832211 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:00:04

All time stamps listed in this document are displayed in GMT

US3832211

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Participant ID

US3832211

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

US3832211

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3832211

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
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

US3832211

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3832211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3832211

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Were any significant conditions reported?

Yes ☒

No ☐

US3832211

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	ANGINA PECTORIS
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	OSTEOARTHRITIS BILATERAL EXTREMITIES
Start date (dd MMM yyyy)	UN DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3832211

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:31 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 15:31
Height (<i>xxx.x</i>)	184.2 cm
Weight (<i>xxx.x</i>)	98.9 kg
BMI (<i>xxx.x</i>)	29.14856 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832211

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

US3832211

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3832211

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 186568

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 ☒

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Height	ND - Not Done
Weight	ND - Not Done

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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)	18 AUG 2020
Time of assessment (00:00-23:59)	15:31 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 15:31
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	51 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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)	18 AUG 2020
Time of assessment (00:00-23:59)	16:51 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:51
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 16:21 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 16:21

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

What was the frequency of the study treatment dosing? ONCE

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

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 AUG 2020

Collection time (00:00-23:59)

16:15 (24 HR)

Collection date and time (derived)

18 AUG 2020 16:15

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:14	18 AUG 2020 16:14
Nasopharyngeal Swab 2	No		

US3832211

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 16:55

PC Open Date & Time

18 AUG 2020 16:41

PC Close Date & Time

18 AUG 2020 19:11

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

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

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

PC Time Stamp 18 AUG 2020 21:24

PC Open Date & Time 18 AUG 2020 20:06

PC Close Date & Time 19 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

98.1 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

19 AUG 2020 12:33

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	21 AUG 2020 11:43
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

21 AUG 2020 17:17

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

22 AUG 2020 19:06

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

23 AUG 2020 12:45

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

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

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

25 AUG 2020 12:01

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 AUG 2020 11:29
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 11

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	28 AUG 2020 15:39
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 12

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 AUG 2020 09:12

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 13

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	30 AUG 2020 14:43
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 14

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

31 AUG 2020 13:05

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 15

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 10:51

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

18 AUG 2020 16:57

PC Open Date & Time

18 AUG 2020 16:41

PC Close Date & Time

18 AUG 2020 19:11

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

18 AUG 2020 21:27

PC Open Date & Time

18 AUG 2020 20:06

PC Close Date & Time

19 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

19 AUG 2020 12:34

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

21 AUG 2020 11:43

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

21 AUG 2020 17:18

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

22 AUG 2020 19:07

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

23 AUG 2020 12:46

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 ☐

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

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 ☐

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 16:56
PC Open Date & Time	18 AUG 2020 16:41
PC Close Date & Time	18 AUG 2020 19:11

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 ☐

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 AUG 2020 20:06

PC Close Date & Time

19 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

65 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:36
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

67 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 11:45
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

69 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 10:11
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

71 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:09
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 ☒

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:47
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 ☐

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

Yes ☐

PC Time stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 11:30
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 AUG 2020 15:37
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 09:13
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

30 AUG 2020 14:44

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 13:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 10:52
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT2

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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)	15 SEP 2020
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:48
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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)	15 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 11:42
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 11:12

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

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

11:06 (24 HR)

Collection date and time (derived)

15 SEP 2020 11:06

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:01	15 SEP 2020 11:01
Nasopharyngeal Swab 2	No		

US3832211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

98.0 °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

15 SEP 2020 11:47

PC Open Date & Time

15 SEP 2020 11:32

PC Close Date & Time

15 SEP 2020 14:02

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp	15 SEP 2020 21:02
PC Open Date & Time	15 SEP 2020 14:57
PC Close Date & Time	16 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

98.6 °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

16 SEP 2020 14:17

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

17 SEP 2020 12:19

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:02

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

19 SEP 2020 14:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 15:07

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 15:49

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 11:48

PC Open Date & Time

15 SEP 2020 11:32

PC Close Date & Time

15 SEP 2020 14:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

15 SEP 2020 21:02

PC Open Date & Time

15 SEP 2020 14:57

PC Close Date & Time

16 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

16 SEP 2020 14:18

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

17 SEP 2020 12:20

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

18 SEP 2020 12:03

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

19 SEP 2020 14:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

20 SEP 2020 15:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

21 SEP 2020 15:50

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 ☐

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 11:48
PC Open Date & Time	15 SEP 2020 11:32
PC Close Date & Time	15 SEP 2020 14:02

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 ☐

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 21:03
PC Open Date & Time	15 SEP 2020 14:57
PC Close Date & Time	16 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

119 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 14:18
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

EAB) (1725)

121 of 2662

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

	Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 12:21
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

EAB) (1725)

123 of 2662

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:04
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

125 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 14:50
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

127 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 15:08
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

129 of 2662

EAB) (1725)

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 15:50
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:23:51

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:23:51

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:28
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

08:46 (24 HR)

Collection date and time (derived)

13 OCT 2020 08:46

US3832211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 13:32:52
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

27 OCT 2020 12:53:15

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 11:46:37
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 10:42:15
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 09:31:17
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

30 NOV 2020 09:48:04

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 17:03:53
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

10 DEC 2020 11:43:40

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 09:53:50

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 09:53:14

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 05:15:48

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 22:16:40

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 21:08:40

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 12:21:55

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 JAN 2021 13:21:32
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 11:02:37
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 23:41:46
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 13:26:05
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 11:28:09
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 08:26:27

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 14:59:41

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 13:14:54

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 15:16:42

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 15:14:21

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 10:00:43

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 10:57:18

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 12:24:17

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	16 AUG 2021 23:59
---	-------------------

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

Patient Cloud Open Date & Time	19 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	23 AUG 2021 23:59
---	-------------------

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

Patient Cloud Open Date & Time	26 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	30 AUG 2021 23:59
---	-------------------

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

Patient Cloud Open Date & Time	24 MAR 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	28 MAR 2022 23:59
---	-------------------

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	29 AUG 2022 23:59
---	-------------------

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

Date and time of submission

Patient Cloud Open Date & Time	20 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	24 OCT 2022 23:59
---	-------------------

US3832211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:00:04

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 18:35:50

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

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

Visit date (dd MMM yyyy)	23 MAR 2021
--------------------------	-------------

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

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

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3832211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	10:17 (24 HR)
Collection date and time (derived)	23 MAR 2021 10:17

US3832211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832211

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:00:04

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3832211

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3832211

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3832211

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Height	72.5 in
Weight	218 lb
BMI (xxx.x)	29.22068

US3832211

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Height	72.5 in
Weight	218 lb
BMI (xxx.x)	29.22068
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)	19 JAN 2021
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 16:04
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Height	72.5 in
Weight	218 lb
BMI (xxx.x)	29.22068
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)	19 JAN 2021
Time of assessment (00:00-23:59)	16:43 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 16:43
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3832211

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 16:13 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 16:13

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

US3832211

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

15:50 (24 HR)

Collection date and time (derived)

19 JAN 2021 15:50

US3832211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	15:48
Collection Date and Time (derived)	19 JAN 2021 15:48

US3832211

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

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)	17 FEB 2021
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 09:40
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

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)	17 FEB 2021
Time of assessment (00:00-23:59)	10:18 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 10:18
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3832211

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 17 FEB 2021

What was the treatment time? (00:00-23:59) 09:46 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 09:46

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

US3832211

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 12:11:39

Generated On: 10 Jun 2021 10:00:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3832211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 12:11:39

Generated On: 10 Jun 2021 10:00:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3832211

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	10:17 (24 HR)
Collection date and time (derived)	23 MAR 2021 10:17

US3832211

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

AEID	USA-US100-2020-MRNA-1273-P30 1000006
Adverse event	COPD EXACERBATION
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)	8 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	9 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2662

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

76 Y/O RANDOMIZED MALE WHO RECEIVED THE FIRST DOSE OF BLINDED MRNA-1273 OR PLACEBO FOR SARS-COV-2 VACCINATION ON 8/18/2020 AND HIS SECOND, FINAL DOSE OF STUDY DRUG, ON 09/15/2020. PRESENTED TO THE ER ON 10/8/2020 WITH WORSENING OF SHORTNESS OF BREATH PER ER RECORDS SPO2 WAS AT 75% PRIOR TO O2 ADMINISTRATION UPON ADMISSION SPO2 WAS AT 94%. SUBJECT STATES HE WAS SEEN BY HIS PULMONOLOGIST 10/7/2020 AND WAS DIAGNOSED WITH A COPD EXACERBATION THE SUBJECT WAS TREATED WITH , PREDNISONE, AND O2 AT 4L. SUBJECT WAS ADMITTED AND TREATED WITH BENZONATATE 200MG TID PRN X7 DAYS, DOXYCYCLINE 100MG 1 PO BID X 7 DAYS, GUAIFENESIN 600MG BID X 7 DAYS IPRATROPIUM-ALBUTEROL 20-100MCG 1 PUFF QID, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. COVID TESTING AS WELL AS INFLUENZA A AND B TESTING COMPLETED BOTH WITH NEGATIVE RESULTS. CHEST XRAY COMPLETED RESULTS WITHIN NORMAL LIMITS.

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)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

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

Yes ☒

No ☐

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication ALBUTEROL SULFATE HFA

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 90

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)

374 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 5000

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)

378 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication DUONEB

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

382 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY

Dose per administration 800

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)

386 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 100

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

If dose unit is Other, specify UNITS/ML

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)

388 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

390 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

394 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication ANGINA

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)

396 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication ROPINIROLE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

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

398 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication SETRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

400 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication SYMBICORT

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 160/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration .4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

404 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

406 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

408 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS BILATERAL
EXTREMITIES

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

410 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication BENZONATATE

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT - CHRONIC
OBSTRUCTIVE PULMONARY
DISEASE EXACERBATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	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)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT - CHRONIC
OBSTRUCTIVE PULMONARY
DISEASE EXACERBATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	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)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication GUAIFENESIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE
EXACERBATION

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	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)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication COMBIVENT RESPIMAT
(IPRATROPIUM ALBUTEROL)

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT - CHRONIC
OBSTRUCTIVE PULMONARY
DISEASE EXACERBATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COPD EXACERBATION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

420 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COPD EXACERBATION

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

422 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	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)	11 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COPD EXACERBATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

424 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication COPD EXACERBATION

Dose per administration 0.004

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

426 of 2662

EAB) (1725)

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 OCT 2020	CHEST X-RAY(WNL)	Adverse Event	
08 OCT 2020	COVID 19 TEST (NEGATIVE)	Adverse Event	
08 OCT 2020	INFLUENZA A AND B TESTING (NEGATIVE)	Adverse Event	

US3832211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:00:04

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3832211

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:00:04

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/OCT/2020 09:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/NOV/2020 14:29
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

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/FEB/2021 10:50
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

US3832211 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832211

Form: Participant Creation

Generated On: 10 Jun 2021 10:00:04

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'US3832211'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:15

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:34:55
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:24

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:34:55
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:16

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:34:55
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:24

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'SCRN'	System	18 Aug 2020 19:10:24

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:17

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '76'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'YEARS'	System	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '76'	System	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered 'Male (M)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered 'l'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Aug 2020'	System	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2020'	System	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Amendment 2 (2)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:16

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'I'	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:35:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:00:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:36:09
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:57

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
Data point term sent to Coder	System	18 Aug 2020 19:12:22
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2005'	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2005'	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:16
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
Data point term sent to Coder	System	18 Aug 2020 19:12:24
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2010'	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2010'	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:13:55
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:28
Data point term sent to Coder	System	18 Aug 2020 19:12:24
User entered 'Atrial Fibrillation'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2010'	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2010'	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:14:45
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
Data point term sent to Coder	System	18 Aug 2020 19:13:27
User entered 'Benign prostatic hyperplasia'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2010'	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2010'	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:15:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29
Data point term sent to Coder	System	18 Aug 2020 19:13:27
User entered 'Diabetes II'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered 'un UNK 2004'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2004'	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2004'	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
Query 'Per DM CLR: Please specify the location and/or type of CHRONIC PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:44:49
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 01:37:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User opened query 'Per DM CLR: Please specify the location and/or type of CHRONIC PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:43:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
Data point term sent to Coder	System	18 Aug 2020 19:13:27
User entered 'Chronic Pain'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:22
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:24
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:27
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:30
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2005'	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2005'	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
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) (b) (4)	18 Aug 2020 23:26:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29
Data point term sent to Coder	System	18 Aug 2020 19:13:30
User entered 'Hypothyroidism'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2014'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2014'	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2014'	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
Data point term sent to Coder	System	18 Aug 2020 19:13:30
User entered 'Allergic Rhinitis'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un Jan 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2020'	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2020'	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:12:41
Data point term sent to Coder	System	23 Sep 2020 14:10:43
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	23 Sep 2020 14:10:13
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'Updated' (Site from System).	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:10:13
Coding entries removed.	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:10:07
User entered 'Angina Pectoris' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:10:07
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:34:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Aug 2020 23:26:29
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	18 Aug 2020 19:13:30
User entered 'Chest pain'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:28
	(b) (4)	

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2000'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2000'	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2000'	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
Data point term sent to Coder	System	18 Aug 2020 19:14:34
User entered 'Restless leg syndrome'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2017'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2017'	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2017'	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
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)	18 Aug 2020 23:26:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:26:34
Data point term sent to Coder	System	18 Aug 2020 19:14:32
User entered 'Depression'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un Jan 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2020'	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2020'	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:26:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:26:32
Data point term sent to Coder	System	18 Aug 2020 19:14:34
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2006'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2006'	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2006'	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
Data point term sent to Coder	System	18 Aug 2020 19:14:36
User entered 'Sleep apnea'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2006'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2006'	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2006'	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 06:29:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 06:29:41
Data point term sent to Coder	System	02 Nov 2020 18:00:23
User entered 'Neuropathy'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'UN UNK 2011'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2011'	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2011'	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:51:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:51:42
Data point term sent to Coder	System	14 Dec 2020 20:51:02
User entered 'HYPERLIPIDEMIA'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'un UNK 2012'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2012'	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2012'	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 21:12:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 21:12:52
Data point term sent to Coder	System	14 Dec 2020 21:12:25
User entered 'OSTEOARTHRITIS Bilateral extremities'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'un Dec 2017'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Dec 2017'	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2017'	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '15:31'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '18 Aug 2020 15:31'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '184.2' cm	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46
DataPoint set to visible.	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '98.9' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46
DataPoint set to visible.	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
Amendment Manager: User entered '29.14856'	System	17 Sep 2020 00:12:44
User entered '29.1'	System	18 Aug 2020 19:44:46
DataPoint set to visible.	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'kg/m2'	System	18 Aug 2020 19:44:46
DataPoint set to visible.	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:43
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:25
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:43
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:20
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:16
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:10
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:28:52
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '97.4' F	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:12:33
Query 'please delete' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:24
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:28:54
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:46
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:41
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:45
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:32
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:28
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:31
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:16
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '70'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'bpm'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'bpm'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:49
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:49
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:47
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:42
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:36
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:37
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '14'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'breaths/min'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'breaths/min'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:52
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:56
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:49
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:50
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:46
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:44
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '102'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'mmHg'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'mmHg'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:13:06
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:13:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:51
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:59
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:51
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:20
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:47:14
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Noted as NCS per Sub-I' (Site from System).	Danyel Johnson (b) (4)	23 Sep 2020 14:10:49
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:12:44
User entered '51'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'mmHg'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'mmHg'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53

US3832211

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:14
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:14

US3832211

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:14
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 15:59:38
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 14:35:23
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:11:14
	(b) (4)	

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54
	(b) (4)	

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User entered 'retired' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54
	(b) (4)	

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:16:25
Query 'Please delete' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:31:10
User entered '0' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:31:02
User opened query 'Please delete' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:39:57
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'This section is for living conditions, please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:16:27
Query 'This section is for living conditions, please verify and reconcile.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:31:16
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:31:02
User opened query 'This section is for living conditions, please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:40:16
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:39:59
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'Plans on routinely (e.g., weekly) going to places where people gather (e.g., places of worship, restaurants, bars, sporting events) over the coming months'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:41
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:41
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:41
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'VISIT1'	System	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:49:33

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:23:50
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:23:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 19:49:33
User entered '186568' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:49:33

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:49:33

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

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)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

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)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:32:21
User closed query 'please enter data' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 15:32:19
Query 'please enter data' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4)	28 Nov 2020 23:40:26
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	28 Nov 2020 23:40:19
User opened query 'please enter data' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:16:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:22:38

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:13:55
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'CORRECTED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:43
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:09:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:42:51
User entered '184.2' cm	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 21:17:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:26:50
Query 'Per source, weight shows inaccurate. Please review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:26:47
User opened query 'Per source, weight shows inaccurate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 01:42:44
User entered '98.8' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:13:55
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'CORRECTED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:43
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:09:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:42:51
User entered '184.2' cm	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Dec 2020 21:17:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:26:50
Query 'Per source, weight shows inaccurate. Please review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:26:47
User opened query 'Per source, weight shows inaccurate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 01:42:44
User entered '98.8' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '15:31'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 15:31'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '97.4' F	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '70'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '14'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '102'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:48:18
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Noted as NCS per Sub-I' (Site from System).	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:11:16
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:12:44
User entered '51'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:13:55
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'CORRECTED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:43
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:09:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:42:51
User entered '184.2' cm	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Dec 2020 21:17:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:26:50
Query 'Per source, weight shows inaccurate. Please review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:26:47
User opened query 'Per source, weight shows inaccurate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 01:42:44
User entered '98.8' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 21:06:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 21:06:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 21:06:07
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:53:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '18 Aug 2020' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:23:47
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 21:06:07
User entered '16:51' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 21:06:07
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:51'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '97.5' F reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '72' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '15' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '95' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '63' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:54:31

US3832211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:43:56
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:54:31

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered '16:21'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:21'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered 'ONCE'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per GCL Lab recon (LB4 - IMMUNO 5) - Sample dated 18 AUG 2020 is reported under Visit 1 Day 1 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit in the response and update if applicable in EDC or PPD Portal. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 06:27:39
Query 'Per GCL Lab recon (LB4 - IMMUNO 5) - Sample dated 18 AUG 2020 is reported under Visit 1 Day 1 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit in the response and update if applicable in EDC or PPD Portal. Thank you.'	Danyel Johnson (b) (4)	14 Dec 2020 21:17:11
answered with 'Immuno samples collected are for Day 1 visit 1 collected 8/18/2020' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab recon (LB4 - IMMUNO 5) - Sample dated 18 AUG 2020 is reported under Visit 1 Day 1 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit in the response and update if applicable in EDC or PPD Portal. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 13:04:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:24
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:55:32
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 18-AUG-2020. However, collection date is missing in GCL. Please confirm if 18-AUG-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 09:02:09
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 18-AUG-2020. However, collection date is missing in GCL. Please confirm if 18-AUG-2020 is correct date to update in GCL records.' answered with 'Per PPD the samples have been received ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 20:46:24
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 18-AUG-2020. However, collection date is missing in GCL. Please confirm if 18-AUG-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:09:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:24
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:55:32

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:24
User entered '16:15'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:55:32

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:15'	System	18 Aug 2020 20:55:32

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered '16:14'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:14'	System	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 19:06:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:12
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:56:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 20:56:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	18 Aug 2020 20:56:04
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered '16:14' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:36
User entered empty.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered empty.	System	11 Nov 2020 19:06:19
User entered '18 Aug 2020 16:14'	System	18 Aug 2020 20:56:36
User entered empty.	System	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:16
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:41

US3832211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'I'	System	18 Aug 2020 20:56:41

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:54:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered 'Yes (Y)'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered '97.5'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered 'No (N)'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered '18 Aug 2020 16:55'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 16:41'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 19:11'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:22:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered 'Yes (Y)'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:23:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf' User entered '97.5'	System	19 Aug 2020 01:24:59
	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:23:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered 'Yes (Y)'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:24:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered '0'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding. ' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:09
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:24:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:30:58
User entered '1'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:24:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered '18 Aug 2020 21:24'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 20:06'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 2'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:30:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered 'Yes (Y)'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:31:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered '98.1'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:31:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered 'Yes (Y)'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:32:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered '0'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:13
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:32:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:32:59
User entered '1'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered '19 Aug 2020 12:33'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 3'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:41:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered 'Yes (Y)'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered '98.0'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered 'Yes (Y)'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:11
User entered '1'	System	21 Aug 2020 15:43:07
	System	21 Aug 2020 15:43:07
	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:23
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:19
User entered '1'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered '21 Aug 2020 11:43'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 4'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:16:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered 'Yes (Y)'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered '98.3'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered 'Yes (Y)'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered '0'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:27
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	(b) (4)	
User entered '1'	System	21 Aug 2020 21:17:52
	System	21 Aug 2020 21:17:52
	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered '21 Aug 2020 17:17'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 5'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered 'Yes (Y)'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:05:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered '98.1'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:05:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered 'Yes (Y)'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered '0'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:31
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	(b) (4)	
User entered '1'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered '22 Aug 2020 19:06'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 6'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered 'Yes (Y)'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered '98.2'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered 'Yes (Y)'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered '0'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:33
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:55
User entered '1'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered '23 Aug 2020 12:45'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 7'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	23 Aug 2020 16:45:13
User entered 'Day 8'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:00:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered 'Yes (Y)'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered '98.5'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered 'Yes (Y)'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:34:04
User entered '1'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered '0'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 9'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:28:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered 'Yes (Y)'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:28:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered '98.5'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:28:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered 'Yes (Y)'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:29:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered '0'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:42
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:29:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:34:27
User entered '1'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:29:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered '27 Aug 2020 11:29'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 10'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:00:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered 'Yes (Y)'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered '98.5'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered 'Yes (Y)'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered '0'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:45
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:35:19
User entered '1'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 15:29:48
User entered 'Day 11'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:38:02', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered 'Yes (Y)'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:38:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered '98.2'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:38:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered 'Yes (Y)'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:39:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered '0'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:49
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:39:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:35:26
User entered '1'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:39:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered '28 Aug 2020 15:39'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 16:01:53
User entered 'Day 12'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:11:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered 'Yes (Y)'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:07', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '98.5'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered 'Yes (Y)'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:35:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '1'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '0'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '30 Aug 2020 09:12'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	28 Aug 2020 19:39:30
User entered 'Day 13'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered 'Yes (Y)'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered '98.6'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered 'Yes (Y)'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered '0'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:54
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:35:39
User entered '1'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered '30 Aug 2020 14:43'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 13:24:30
User entered 'Day 14'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered 'Yes (Y)'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered '98.6'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered 'Yes (Y)'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:35:52
User entered '1'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:59
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:35:50
User entered '1'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered '31 Aug 2020 13:05'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 18:43:54
User entered 'Day 15'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered 'Yes (Y)'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered '98.3'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered 'No (N)'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered '02 Sep 2020 10:51'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'None (1)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'No (N)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'No (N)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'None (1)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered '18 Aug 2020 16:57'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 16:41'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 19:11'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:25:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'None (1)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:25:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'No (N)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:25:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'No (N)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:26:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'None (1)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:27:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered '18 Aug 2020 21:27'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 20:06'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 2'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'None (1)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'No (N)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'No (N)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'None (1)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:34:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered '19 Aug 2020 12:34'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 3'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'None (1)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'No (N)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'No (N)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'None (1)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered '21 Aug 2020 11:43'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 4'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:07', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'None (1)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'No (N)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'No (N)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'None (1)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered '21 Aug 2020 17:18'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 5'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'None (1)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'No (N)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'No (N)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'None (1)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered '22 Aug 2020 19:07'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 6'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'None (1)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'No (N)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'No (N)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'None (1)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered '23 Aug 2020 12:46'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 7'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'No (N)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered '18 Aug 2020 16:56'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 16:41'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 19:11'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 20:06'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 2'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:34:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:36:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:36:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'No (N)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:36:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered '19 Aug 2020 12:36'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 3'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:06', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'No (N)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered '21 Aug 2020 11:45'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 4'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:10:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:10:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:11:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'No (N)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:11:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered '22 Aug 2020 10:11'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 5'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:08:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:08:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'No (N)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered '22 Aug 2020 19:09'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 6'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered 'None (0)'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered 'None (0)'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered 'None (0)'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered 'None (0)'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered 'None (0)'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:47:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered 'None (0)'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:47:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered 'No (N)'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:47:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf'	System	23 Aug 2020 16:47:22
User entered '23 Aug 2020 12:47'	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 7'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	23 Aug 2020 16:45:13
User entered 'Day 8'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5fd7ede2-a63d-4566-a9a0-85795229019a'	System	25 Aug 2020 16:02:29
User entered 'No (N)'	System	25 Aug 2020 16:02:29

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5fd7ede2-a63d-4566-a9a0-85795229019a'	System	25 Aug 2020 16:02:29
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:02:29

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 9'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:30:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '81114c94-5128-4365-96bb-f20cf8f8b38e'	System	27 Aug 2020 15:30:30
User entered 'No (N)'	System	27 Aug 2020 15:30:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:30:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '81114c94-5128-4365-96bb-f20cf8f8b38e'	System	27 Aug 2020 15:30:30
User entered '27 Aug 2020 11:30'	System	27 Aug 2020 15:30:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 10'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8b4e877f-b5a3-42da-86c5-bf75c4132b5d'	System	27 Aug 2020 16:02:26
User entered 'No (N)'	System	27 Aug 2020 16:02:26

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8b4e877f-b5a3-42da-86c5-bf75c4132b5d'	System	27 Aug 2020 16:02:26
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:02:26

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 15:29:48
User entered 'Day 11'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:37:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8c92d6dc-5a30-4848-85fe-12d8046dfa14'	System	28 Aug 2020 19:37:48
User entered 'No (N)'	System	28 Aug 2020 19:37:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:37:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8c92d6dc-5a30-4848-85fe-12d8046dfa14'	System	28 Aug 2020 19:37:48
User entered '28 Aug 2020 15:37'	System	28 Aug 2020 19:37:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 16:01:53
User entered 'Day 12'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:13:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '08362b3b-8643-4932-a47a-0000e983267f'	System	30 Aug 2020 13:14:40
User entered 'No (N)'	System	30 Aug 2020 13:14:40

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:13:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '08362b3b-8643-4932-a47a-0000e983267f'	System	30 Aug 2020 13:14:40
User entered '30 Aug 2020 09:13'	System	30 Aug 2020 13:14:40

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	28 Aug 2020 19:39:30
User entered 'Day 13'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:44:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '43958f30-ba73-45cb-8b8f-c9dd66d716f0'	System	30 Aug 2020 18:44:30
User entered 'No (N)'	System	30 Aug 2020 18:44:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:44:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '43958f30-ba73-45cb-8b8f-c9dd66d716f0'	System	30 Aug 2020 18:44:30
User entered '30 Aug 2020 14:44'	System	30 Aug 2020 18:44:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 13:24:30
User entered 'Day 14'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:04:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '22c88ef8-6fe0-4443-a041-71406be9a043'	System	31 Aug 2020 17:15:52
User entered 'No (N)'	System	31 Aug 2020 17:15:52

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:04:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '22c88ef8-6fe0-4443-a041-71406be9a043'	System	31 Aug 2020 17:15:52
User entered '31 Aug 2020 13:04'	System	31 Aug 2020 17:15:52

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 18:43:54
User entered 'Day 15'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:52:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '860ba4a0-efbc-4ca7-91ce-156281115b62'	System	02 Sep 2020 14:52:16
User entered 'No (N)'	System	02 Sep 2020 14:52:16

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:52:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '860ba4a0-efbc-4ca7-91ce-156281115b62'	System	02 Sep 2020 14:52:16
User entered '02 Sep 2020 10:52'	System	02 Sep 2020 14:52:16

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:43:54

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered 'Yes (Y)'	Emma Partin (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered '25 Aug 2020'	Emma Partin (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4) (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered empty.	Emma Partin (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:48:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	01 Sep 2020 13:46:22

US3832211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'I'	System	01 Sep 2020 13:46:22

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered '1 Sep 2020'	Alyssa-Kay Peay (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Sep 2020 13:46:35

US3832211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered 'I'	System	01 Sep 2020 13:46:35

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '8 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	08 Sep 2020 14:36:11

US3832211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered 'I'	System	08 Sep 2020 14:36:11

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:23

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:23

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:23

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'VISIT2'	System	15 Sep 2020 14:35:23

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '10:48'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 10:48'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '98.3' F	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Oral (Oral)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '88'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '16'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '154'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '77'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '11:42'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:42'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '98.0' F	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Oral (Oral)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '50'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '16'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '131'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 12:37:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Noted as NCS as per Sub-I' (Site from System).	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:11:42
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:12:44
User entered '56'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:33

US3832211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:33

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '11:12'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:12'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'ONCE'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '11:06'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is updated with 15SEP2020 in EDC. Please review the dates and update as required.Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 05:44:17
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is updated with 15SEP2020 in EDC. Please review the dates and update as required.Else clarify, thank you. ' answered with 'DCF Will be created to correct reported date in PPD' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:18:31
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is updated with 15SEP2020 in EDC. Please review the dates and update as required.Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:05:43
User entered '15 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '11:01' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:33
User entered '11:06' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:19
User entered '11:01'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:07:33
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 15:07:19
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:34
User entered 'Yes (Y)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:02:38
	(b) (4)	

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:34
User entered '11:01' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:33
User entered '11:06' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:19
User entered '11:01'	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered empty.	System	11 Nov 2020 19:06:34
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:07:33
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 15:07:19
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:39

US3832211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'I'	System	15 Sep 2020 14:35:39

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered 'Yes (Y)'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered '98.0'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered 'No (N)'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered '15 Sep 2020 11:47'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 11:32'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:01:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered 'Yes (Y)'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:01:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered '98.3'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:01:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered 'No (N)'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:57'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 2'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered 'Yes (Y)'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered '98.6'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered 'No (N)'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered '16 Sep 2020 14:17'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 3'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:18:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered 'Yes (Y)'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:18:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered '97.6'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:18:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered 'No (N)'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered '17 Sep 2020 12:19'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 4'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered '98.1'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered 'No (N)'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered '18 Sep 2020 12:02'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 5'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:48:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered 'Yes (Y)'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered '97.8'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered 'No (N)'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered '19 Sep 2020 14:49'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 6'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:08', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered 'Yes (Y)'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered '98.2'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered 'No (N)'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered '20 Sep 2020 15:07'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 7'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:48:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered 'Yes (Y)'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered '98.5'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered 'No (N)'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'None (1)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'No (N)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'No (N)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'None (1)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered '15 Sep 2020 11:48'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 11:32'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'None (1)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'No (N)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'No (N)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'None (1)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:57'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 2'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'None (1)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'No (N)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'No (N)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'None (1)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered '16 Sep 2020 14:18'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 3'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'None (1)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'No (N)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'No (N)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'None (1)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered '17 Sep 2020 12:20'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 4'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'None (1)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'No (N)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'No (N)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'None (1)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered '18 Sep 2020 12:03'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 5'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'None (1)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'No (N)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'No (N)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'None (1)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered '19 Sep 2020 14:49'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 6'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'None (1)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'No (N)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'No (N)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'None (1)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered '20 Sep 2020 15:08'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 7'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'None (1)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'No (N)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'No (N)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'None (1)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered '21 Sep 2020 15:50'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'No (N)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered '15 Sep 2020 11:48'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 11:32'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'No (N)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered '15 Sep 2020 21:03'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:57'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 2'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'No (N)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered '16 Sep 2020 14:18'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 3'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'Yes (Y)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:21:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered '17 Sep 2020 12:21'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 4'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'No (N)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 5'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:08', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered 'No (N)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becd4'	System	19 Sep 2020 18:50:52
User entered '19 Sep 2020 14:50'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 6'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'No (N)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered '20 Sep 2020 15:08'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 7'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'No (N)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered '21 Sep 2020 15:50'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '23 Sep 2020'	(b) (4) Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4)	23 Sep 2020 14:07:47

US3832211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered 'I'	System	23 Sep 2020 14:07:47

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:23

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered '29 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:23

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:23

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered empty.	Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:23

US3832211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:30

US3832211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered 'I'	System	29 Sep 2020 15:05:30

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '06 Oct 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	06 Oct 2020 15:42:31

US3832211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered 'I'	System	06 Oct 2020 15:42:31

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'VISIT3'	System	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '08:28'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '13 Oct 2020 08:28'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '98.1' F	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Oral (Oral)'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '80'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '17'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '146'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '65'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29

US3832211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:09

US3832211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:37:09

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '08:46'	Emma Partin (b) (4)	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '13 Oct 2020 08:46'	System	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:43

US3832211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'I'	System	13 Oct 2020 14:37:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 64'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-20T13:31:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1328f857-9b39-4ec3-80f2-68e75d308fc7'	System	20 Oct 2020 17:32:57
User entered 'No (N)'	System	20 Oct 2020 17:32:57

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-20T13:30:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1328f857-9b39-4ec3-80f2-68e75d308fc7'	System	20 Oct 2020 17:32:57
User entered 'No (N)'	System	20 Oct 2020 17:32:57

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-20T13:32:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1328f857-9b39-4ec3-80f2-68e75d308fc7'	System	20 Oct 2020 17:32:57
User entered '20 Oct 2020 13:32:52'	System	20 Oct 2020 17:32:57

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 71'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-27T12:52:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0db3da34-6d06-49f9-8eaa-fcf16bc529c9'	System	27 Oct 2020 16:53:20
User entered 'No (N)'	System	27 Oct 2020 16:53:20

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-27T12:47:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0db3da34-6d06-49f9-8eaa-fcf16bc529c9'	System	27 Oct 2020 16:53:20
User entered 'No (N)'	System	27 Oct 2020 16:53:20

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-27T12:53:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0db3da34-6d06-49f9-8eaa-fcf16bc529c9'	System	27 Oct 2020 16:53:20
User entered '27 Oct 2020 12:53:15'	System	27 Oct 2020 16:53:20

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 78'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-03T11:46:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'be52bcfe-1534-4414-b730-c3bb6f55adf8'	System	03 Nov 2020 16:46:43
User entered 'No (N)'	System	03 Nov 2020 16:46:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-03T11:46:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'be52bcfe-1534-4414-b730-c3bb6f55adf8'	System	03 Nov 2020 16:46:43
User entered 'No (N)'	System	03 Nov 2020 16:46:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-03T11:46:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'be52bcfe-1534-4414-b730-c3bb6f55adf8'	System	03 Nov 2020 16:46:43
User entered '03 Nov 2020 11:46:37'	System	03 Nov 2020 16:46:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 92'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-17T10:41:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5ef9328a-4330-4944-a71e-667fa39c01ed'	System	17 Nov 2020 15:42:18
User entered 'No (N)'	System	17 Nov 2020 15:42:18

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-17T10:41:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5ef9328a-4330-4944-a71e-667fa39c01ed'	System	17 Nov 2020 15:42:18
User entered 'No (N)'	System	17 Nov 2020 15:42:18

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-17T10:42:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5ef9328a-4330-4944-a71e-667fa39c01ed'	System	17 Nov 2020 15:42:18
User entered '17 Nov 2020 10:42:15'	System	17 Nov 2020 15:42:18

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-22T09:30:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4226d0de-360f-445c-b5c1-71dbaef97469'	System	22 Nov 2020 14:31:22
User entered 'No (N)'	System	22 Nov 2020 14:31:22

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-22T09:31:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4226d0de-360f-445c-b5c1-71dbaef97469'	System	22 Nov 2020 14:31:22
User entered 'No (N)'	System	22 Nov 2020 14:31:22

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-22T09:31:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4226d0de-360f-445c-b5c1-71dbaef97469'	System	22 Nov 2020 14:31:22
User entered '22 Nov 2020 09:31:17'	System	22 Nov 2020 14:31:22

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-30T09:47:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6b287e8a-01c6-43ae-aba2-37479ada500c'	System	30 Nov 2020 14:48:08
User entered 'No (N)'	System	30 Nov 2020 14:48:08

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-30T09:47:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6b287e8a-01c6-43ae-aba2-37479ada500c'	System	30 Nov 2020 14:48:08
User entered 'No (N)'	System	30 Nov 2020 14:48:08

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-30T09:48:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6b287e8a-01c6-43ae-aba2-37479ada500c'	System	30 Nov 2020 14:48:08
User entered '30 Nov 2020 09:48:04'	System	30 Nov 2020 14:48:08

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-03T17:03:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '57d233d6-3514-4115-a6fa-b51e4c8980b1'	System	03 Dec 2020 22:03:59
User entered 'No (N)'	System	03 Dec 2020 22:03:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-03T17:03:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '57d233d6-3514-4115-a6fa-b51e4c8980b1'	System	03 Dec 2020 22:03:59
User entered 'No (N)'	System	03 Dec 2020 22:03:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-03T17:03:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '57d233d6-3514-4115-a6fa-b51e4c8980b1' User entered '03 Dec 2020 17:03:53'	System	03 Dec 2020 22:03:59
	System	03 Dec 2020 22:03:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-10T11:43:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '88816bc0-dfbd-4e1c-9d93-55f73ac1a0d9'	System	10 Dec 2020 16:43:44
User entered 'No (N)'	System	10 Dec 2020 16:43:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-10T11:43:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '88816bc0-dfbd-4e1c-9d93-55f73ac1a0d9'	System	10 Dec 2020 16:43:44
User entered 'No (N)'	System	10 Dec 2020 16:43:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-10T11:43:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '88816bc0-dfbd-4e1c-9d93-55f73ac1a0d9' User entered '10 Dec 2020 11:43:40'	System	10 Dec 2020 16:43:44
	System	10 Dec 2020 16:43:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-17T09:53:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dc96b05d-7784-49af-ac6d-f0f968ba0c12'	System	17 Dec 2020 14:53:54
User entered 'No (N)'	System	17 Dec 2020 14:53:54

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-17T09:53:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dc96b05d-7784-49af-ac6d-f0f968ba0c12'	System	17 Dec 2020 14:53:54
User entered 'No (N)'	System	17 Dec 2020 14:53:54

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-17T09:53:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dc96b05d-7784-49af-ac6d-f0f968ba0c12'	System	17 Dec 2020 14:53:54
User entered '17 Dec 2020 09:53:50'	System	17 Dec 2020 14:53:54

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-24T09:52:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a1dfc61-c35d-4656-a5ca-7e2192dcd232'	System	24 Dec 2020 14:53:16
User entered 'No (N)'	System	24 Dec 2020 14:53:16

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-24T09:53:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a1dfc61-c35d-4656-a5ca-7e2192dcd232'	System	24 Dec 2020 14:53:16
User entered 'No (N)'	System	24 Dec 2020 14:53:16

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-24T09:53:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a1dfc61-c35d-4656-a5ca-7e2192dcd232'	System	24 Dec 2020 14:53:16
User entered '24 Dec 2020 09:53:14'	System	24 Dec 2020 14:53:16

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-31T05:15:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6e0ae5a7-ccd4-4fe5-995b-1982f69db605'	System	31 Dec 2020 10:15:50
User entered 'No (N)'	System	31 Dec 2020 10:15:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-31T05:15:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6e0ae5a7-ccd4-4fe5-995b-1982f69db605'	System	31 Dec 2020 10:15:50
User entered 'No (N)'	System	31 Dec 2020 10:15:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-31T05:15:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6e0ae5a7-ccd4-4fe5-995b-1982f69db605' User entered '31 Dec 2020 05:15:48'	System	31 Dec 2020 10:15:50
	System	31 Dec 2020 10:15:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-09T22:16:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5e075ad4-892f-46db-a0b3-55fee65d7d11'	System	10 Jan 2021 03:16:42
User entered 'No (N)'	System	10 Jan 2021 03:16:42

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-09T22:16:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5e075ad4-892f-46db-a0b3-55fee65d7d11'	System	10 Jan 2021 03:16:42
User entered 'No (N)'	System	10 Jan 2021 03:16:42

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-09T22:16:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5e075ad4-892f-46db-a0b3-55fee65d7d11' User entered '09 Jan 2021 22:16:40'	System	10 Jan 2021 03:16:42

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-15T21:08:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9a187a00-be66-4f71-9f4d-6e3be51a59dc'	System	16 Jan 2021 02:08:50
User entered 'No (N)'	System	16 Jan 2021 02:08:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-15T21:08:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9a187a00-be66-4f71-9f4d-6e3be51a59dc'	System	16 Jan 2021 02:08:50
User entered 'No (N)'	System	16 Jan 2021 02:08:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-15T21:08:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9a187a00-be66-4f71-9f4d-6e3be51a59dc'	System	16 Jan 2021 02:08:50
User entered '15 Jan 2021 21:08:40'	System	16 Jan 2021 02:08:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-21T12:21:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b4ab0a0e-8987-41ae-8fde-f5bdbc9c92bc'	System	21 Jan 2021 17:21:55
User entered 'No (N)'	System	21 Jan 2021 17:21:55

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-21T12:21:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b4ab0a0e-8987-41ae-8fde-f5bdbc9c92bc'	System	21 Jan 2021 17:21:55
User entered 'No (N)'	System	21 Jan 2021 17:21:55

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-21T12:21:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b4ab0a0e-8987-41ae-8fde-f5bdbc9c92bc'	System	21 Jan 2021 17:21:55
User entered '21 Jan 2021 12:21:55'	System	21 Jan 2021 17:21:55

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-28T13:20:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'Yes (Y)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-28T13:20:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'No (N)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-28T13:20:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'No (N)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-28T13:21:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'No (N)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-28T13:21:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered '28 Jan 2021 13:21:32'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-04T11:01:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7fda08ae-cda9-4326-a279-473fca2b7952'	System	04 Feb 2021 16:02:41
User entered 'No (N)'	System	04 Feb 2021 16:02:41

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-04T11:02:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7fda08ae-cda9-4326-a279-473fca2b7952'	System	04 Feb 2021 16:02:41
User entered 'No (N)'	System	04 Feb 2021 16:02:41

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-04T11:02:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7fda08ae-cda9-4326-a279-473fca2b7952'	System	04 Feb 2021 16:02:41
User entered '04 Feb 2021 11:02:37'	System	04 Feb 2021 16:02:41

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-13T23:41:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '67c2a57c-02d7-4305-8ea0-dcf08a7203fe'	System	14 Feb 2021 04:41:48
User entered 'No (N)'	System	14 Feb 2021 04:41:48

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-13T23:41:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '67c2a57c-02d7-4305-8ea0-dcf08a7203fe'	System	14 Feb 2021 04:41:48
User entered 'No (N)'	System	14 Feb 2021 04:41:48

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-13T23:41:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '67c2a57c-02d7-4305-8ea0-dcf08a7203fe'	System	14 Feb 2021 04:41:48
User entered '13 Feb 2021 23:41:46'	System	14 Feb 2021 04:41:48

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-18T13:25:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3d940be3-87f8-4c81-b68e-2967ba998afc'	System	18 Feb 2021 18:26:12
User entered 'No (N)'	System	18 Feb 2021 18:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-18T13:25:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3d940be3-87f8-4c81-b68e-2967ba998afc'	System	18 Feb 2021 18:26:12
User entered 'No (N)'	System	18 Feb 2021 18:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-18T13:26:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3d940be3-87f8-4c81-b68e-2967ba998afc'	System	18 Feb 2021 18:26:12
User entered '18 Feb 2021 13:26:05'	System	18 Feb 2021 18:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-25T11:27:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '23e54c85-d387-41d0-bb6c-9e0b5a2b57ba'	System	26 Feb 2021 03:44:19
User entered 'No (N)'	System	26 Feb 2021 03:44:19

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-25T11:28:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '23e54c85-d387-41d0-bb6c-9e0b5a2b57ba'	System	26 Feb 2021 03:44:19
User entered 'No (N)'	System	26 Feb 2021 03:44:19

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-25T11:28:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '23e54c85-d387-41d0-bb6c-9e0b5a2b57ba'	System	26 Feb 2021 03:44:19
User entered '25 Feb 2021 11:28:09'	System	26 Feb 2021 03:44:19

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-04T08:26:07', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1cc8b05d-10af-42e1-b3f6-6d97625eb119'	System	04 Mar 2021 13:26:30
User entered 'No (N)'	System	04 Mar 2021 13:26:30

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-04T08:26:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1cc8b05d-10af-42e1-b3f6-6d97625eb119'	System	04 Mar 2021 13:26:30
User entered 'No (N)'	System	04 Mar 2021 13:26:30

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-04T08:26:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1cc8b05d-10af-42e1-b3f6-6d97625eb119'	System	04 Mar 2021 13:26:30
User entered '04 Mar 2021 08:26:27'	System	04 Mar 2021 13:26:30

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-11T14:59:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe16e44-35be-481b-a870-66224c22c52d'	System	11 Mar 2021 19:59:44
User entered 'No (N)'	System	11 Mar 2021 19:59:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-11T14:59:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe16e44-35be-481b-a870-66224c22c52d'	System	11 Mar 2021 19:59:44
User entered 'No (N)'	System	11 Mar 2021 19:59:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-11T14:59:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe16e44-35be-481b-a870-66224c22c52d'	System	11 Mar 2021 19:59:44
User entered '11 Mar 2021 14:59:41'	System	11 Mar 2021 19:59:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-03-25T13:14:39-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f0ae954c-fd36-4eb1-a49e-436f6cabfdca' User entered 'No (N)'	System	25 Mar 2021 17:15:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-03-25T13:14:44-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f0ae954c-fd36-4eb1-a49e-436f6cabfdca' User entered 'No (N)'	System	25 Mar 2021 17:15:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-03-25T13:14:54-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f0ae954c-fd36-4eb1-a49e-436f6cabfdca' User entered '25 Mar 2021 13:14:54'	System	25 Mar 2021 17:15:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-04-05T15:16:26-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ad1055de-6be8-4fe8-8842-e49779e471d1'	System	05 Apr 2021 19:16:51
User entered 'No (N)'	System	05 Apr 2021 19:16:51

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-04-05T15:16:30-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ad1055de-6be8-4fe8-8842-e49779e471d1'	System	05 Apr 2021 19:16:51
User entered 'No (N)'	System	05 Apr 2021 19:16:51

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-04-05T15:16:42-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ad1055de-6be8-4fe8-8842-e49779e471d1'	System	05 Apr 2021 19:16:51
User entered '05 Apr 2021 15:16:42'	System	05 Apr 2021 19:16:51

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-12T15:14:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a286b85a-b0f6-4be7-96ee-8e713f808d68' User entered 'No (N)'	System	12 Apr 2021 19:14:24
	System	12 Apr 2021 19:14:24

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-12T15:14:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a286b85a-b0f6-4be7-96ee-8e713f808d68'	System	12 Apr 2021 19:14:24
User entered 'No (N)'	System	12 Apr 2021 19:14:24

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-12T15:14:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a286b85a-b0f6-4be7-96ee-8e713f808d68' User entered '12 Apr 2021 15:14:21'	System	12 Apr 2021 19:14:24
	System	12 Apr 2021 19:14:24

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-15T10:00:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'effc7ad5-70d0-472b-98df-6c7ba6f14ab4'	System	15 Apr 2021 14:01:40
User entered 'No (N)'	System	15 Apr 2021 14:01:40

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-15T10:00:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'effc7ad5-70d0-472b-98df-6c7ba6f14ab4'	System	15 Apr 2021 14:01:40
User entered 'No (N)'	System	15 Apr 2021 14:01:40

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-15T10:00:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'effc7ad5-70d0-472b-98df-6c7ba6f14ab4' User entered '15 Apr 2021 10:00:43'	System	15 Apr 2021 14:01:40
	System	15 Apr 2021 14:01:40

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-22T10:56:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'de9de251-cf60-4eaf-8ca5-fddf2e8d082b' User entered 'No (N)'	System	22 Apr 2021 14:57:23

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-22T10:56:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'de9de251-cf60-4eaf-8ca5-fddf2e8d082b' User entered 'No (N)'	System	22 Apr 2021 14:57:23

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-22T10:57:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'de9de251-cf60-4eaf-8ca5-fddf2e8d082b' User entered '22 Apr 2021 10:57:18'	System	22 Apr 2021 14:57:23

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-29T12:23:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '27c6a147-d232-46c7-a400-825263b17bdf' User entered 'No (N)'	System	29 Apr 2021 16:24:47
	System	29 Apr 2021 16:24:47

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-29T12:23:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '27c6a147-d232-46c7-a400-825263b17bdf' User entered 'No (N)'	System	29 Apr 2021 16:24:47

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-29T12:24:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '27c6a147-d232-46c7-a400-825263b17bdf' User entered '29 Apr 2021 12:24:17'	System	29 Apr 2021 16:24:47
	System	29 Apr 2021 16:24:47

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:04

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:47:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-27T18:35:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'e18b7048-aaa9-49c8-bb70-95d12cb2c49c'	System	27 Feb 2021 23:35:51
User entered 'No (N)'	System	27 Feb 2021 23:35:51

US3832211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:04

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:47:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-27T18:35:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'e18b7048-aaa9-49c8-bb70-95d12cb2c49c'	System	27 Feb 2021 23:35:51
User entered '27 Feb 2021 18:35:50'	System	27 Feb 2021 23:35:51

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '10 Nov 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:23

US3832211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'I'	System	10 Nov 2020 17:20:23

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '11 Dec 2020'	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:20

US3832211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User entered 'I'	System	11 Dec 2020 16:49:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '11 Jan 2021'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:24

US3832211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User entered 'I'	System	11 Jan 2021 14:43:24

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '15 Feb 2021'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42

US3832211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:48

US3832211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User entered 'I'	System	15 Feb 2021 16:00:48

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:52:51

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:52:51

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:52:51

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered 'VISIT4'	System	12 Apr 2021 16:52:51

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18

US3832211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:42

US3832211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:42

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:08

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:08

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '10:17'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:08

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered '23 Mar 2021 10:17'	System	12 Apr 2021 16:54:08

US3832211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:15

US3832211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered 'I'	System	12 Apr 2021 16:54:15

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:27
	(b) (4)	

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
	(b) (4)	
User entered '12 Apr 2021'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:27
	(b) (4)	

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:27
	(b) (4)	

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:27
	(b) (4)	

US3832211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:35
	(b) (4)	

US3832211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 16:54:35

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '0'	Rodolfo Barrera (b) (4)	08 Apr 2021 13:11:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:02:12

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 01:54:14
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated.' (Site from DM).	Rodolfo Barrera (b) (4)	08 Apr 2021 13:12:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rodolfo Barrera (b) (4)	08 Apr 2021 13:11:57
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:09:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:02:12

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:38:51
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:38:51
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '1'	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'I'	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '72.5' in	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '218' lb	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '29.22068'	System	19 Jan 2021 22:18:02
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '72.5' in	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '218' lb	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '29.22068'	System	19 Jan 2021 22:18:02
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16:04'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 16:04'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '97.8' F	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Oral (Oral)'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '74'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'bpm'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '14'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'breaths/min'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '113'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '65'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '72.5' in	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '218' lb	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '29.22068'	System	19 Jan 2021 22:18:02
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16:43'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 16:43'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '98.8' F	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Oral (Oral)'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '75'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'bpm'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'breaths/min'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '130'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '77'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:08:35

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:08:35

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mRNA-1273'	System	19 Jan 2021 21:23:41
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16:13'	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 16:13'	System	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Left Arm (LEFT ARM)'	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'ONCE'	System	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '15:50'	Emma Partin (b) (4)	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 15:50'	System	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '15:48'	Emma Partin (b) (4)	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 15:48'	System	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:08:28

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '1'	System	19 Jan 2021 21:08:28

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15
	(b) (4)	

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '26 Jan 2021'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15
	(b) (4)	

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15
	(b) (4)	

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15
	(b) (4)	

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:18
	(b) (4)	

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User entered '1'	System	26 Jan 2021 17:31:18

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User entered 'I'	System	26 Jan 2021 17:31:18
DataPoint set to visible.	System	26 Jan 2021 17:31:18

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	Emma Partin (b) (4)	17 Feb 2021 15:08:37

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:08:37

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	17 Feb 2021 15:08:37

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'OLD29'	System	17 Feb 2021 15:08:37

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '09:40'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered '17 Feb 2021 09:40'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '97.9' F	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '79'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'bpm'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '13'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'breaths/min'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '111'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '66'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '10:18'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered '17 Feb 2021 10:18'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '97.9' F	Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '81'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'bpm'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '14'	Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'breaths/min'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '118'	Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '70'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	Emma Partin (b) (4)	17 Feb 2021 15:08:43

US3832211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:08:43

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mRNA-1273'	System	17 Feb 2021 15:09:00
DataPoint set to visible.	System	26 Jan 2021 17:31:18

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '09:46'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered '17 Feb 2021 09:46'	System	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Left Arm (LEFT ARM)'	Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'ONCE'	System	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	Emma Partin (b) (4)	17 Feb 2021 15:09:05

US3832211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'I'	System	17 Feb 2021 15:09:05

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered '24 Feb 2021'	Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered empty.	Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46

US3832211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User closed query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 23 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.	(b) (4), (b) (6)	08 Apr 2021 15:21:57
' (Site from DM). Query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 23 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.	Danyel Johnson (b) (4)	06 Apr 2021 19:42:40
' answered with 'Updated per review of source ' (Site from DM). User opened query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 23 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.	(b) (4), (b) (6)	06 Apr 2021 08:55:28
' (Site from DM). User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered 'Yes (Y)'	(b) (4) Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:51

US3832211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User entered 'I'	System	24 Feb 2021 17:09:51

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	Danyel Johnson (b) (4)	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered 'OLD57'	System	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27
	(b) (4)	

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56

US3832211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	Danyel Johnson (b) (4)	06 Apr 2021 19:15:06

US3832211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4)	06 Apr 2021 19:15:06

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	06 Apr 2021 19:15:33

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	Danyel Johnson (b) (4)	06 Apr 2021 19:15:33

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '10:17'	Danyel Johnson (b) (4)	06 Apr 2021 19:15:33

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered '23 Mar 2021 10:17'	System	06 Apr 2021 19:15:33

US3832211

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:00:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:52
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:36:05
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:43:00

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:23
User entered	System	14 Oct 2020 13:41:15
'USA-US100-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 13:41:15

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:52:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:52:29
Data point term sent to Coder	System	13 Oct 2020 13:51:24
User entered 'COPD Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 21:54:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 21:54:15
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 13:51:06
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '8 Oct 2020'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:02
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:37:53
User entered 'No (N)' reason for change: New Information	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:37:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Yes (Y)' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 23:33:22
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' answered with 'Data is entered as correct as reported' (Site from DM).	Danyel Johnson (b) (4)	26 Apr 2021 14:38:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	26 Apr 2021 14:29:40
DataPoint Verified.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Un-verified.	(b) (4)	
User entered '16 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 17:14:04
DataPoint Verified.	Danyel Johnson (b) (4)	12 Nov 2020 14:37:53
User entered empty; reason for change New Information	(b) (4)	
User entered '9 Oct 2020'	Danyel Johnson (b) (4)	12 Nov 2020 14:37:53
	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:54:15
	(b) (4)	
	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:13:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:57:17
User entered empty.	System	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Yes (Y)' reason for change: New Information	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:54:15
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 06:42:06
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admission dates are entered as 08 OCT 2020- 09 OT 2020' (Site from System).	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:55:11
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 21:54:15
User entered '1' reason for change: New Information	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:54:15
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '8 Oct 2020' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '9 Oct 2020' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 21:54:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 21:54:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 13:51:06
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 21:54:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 21:54:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 13:51:06
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Not Applicable (NOT APPLICABLE)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'I'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:16:38
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:28:51
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Data updated per subject report' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:38:13
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Danyel Johnson (b) (4)	12 Nov 2020 14:37:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:56:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:54:15
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:50:25
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 20:01:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:01:11
User closed query 'Per DM CLR: Narrative indicates that the subject was treated with O2 at 4L. However, there is no recorded ConMed that match this treatment. Please update to record the corresponding treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:50:38
Query 'Per DM CLR: Narrative indicates that the subject was treated with O2 at 4L. However, there is no recorded ConMed that match this treatment. Please update to record the corresponding treatment as appropriate. Otherwise, clarify.' answered with 'Reviewed and updated per review' (Site from DM).	Danyel Johnson (b) (4)	29 Mar 2021 18:46:33
User opened query 'Per DM CLR: Narrative indicates that the subject was treated with O2 at 4L. However, there is no recorded ConMed that match this treatment. Please update to record the corresponding treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 19:11:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
User entered '76 Y/O RANDOMIZED MALE WHO RECEIVED THE FIRST DOSE OF BLINDED MRNA-1273 OR PLACEBO FOR SARS-COV-2 VACCINATION ON 8/18/2020 AND HIS SECOND, FINAL DOSE OF STUDY DRUG, ON 09/15/ 2020. PRESENTED TO THE ER ON 10/8/2020 WITH WORSENING OF SHORTNESS OF BREATH PER ER RECORDS SPO2 WAS AT 75% PRIOR TO O2 ADMINISTRATION UPON ADMISSION SPO2 WAS AT 94%. SUBJECT STATES HE WAS SEEN BY HIS PULMONOLOGIST 10/7/2020 AND WAS DIAGNOSED WITH A COPD EXACERBATION THE SUBJECT WAS TREATED WITH , PREDNISONE, AND O2 AT 4L. SUBJECT WAS ADMITTED AND TREATED WITH BENZONATATE 200MG TID PRN X7 DAYS, DOXYCYCLINE 100MG 1 PO BID X 7 DAYS, GUAIFENESIN 600MG BID X 7 DAYS IPRATROPIUM-ALBUTEROL 20-100MCG 1 PUFF QID, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. COVID TESTING AS WELL AS INFLUENZA A AND B TESTING COMPLETED BOTH WITH NEGATIVE RESULTS. CHEST XRAY COMPLETED RESULTS WITHIN NORMAL LIMITS.' reason for change: New Information	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:03:51
User closed query 'Per DM CLR: Narrative indicates that the subject received Levaquin, Prednisone and Oxygen at 4 L/min rate. However, there is no corresponding ConMed record that match these information. Please review and update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:47:49

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject received Levaquin, Prednisone and Oxygen at 4 L/min rate. However, there is no corresponding ConMed record that match these information. Please review and update to record the corresponding medications as appropriate. Otherwise, clarify.' answered with 'Review of records indicate prednisone and O2 however the subject was given Doxycycline and not levaquin, levaquin was reported in error' (Site from DM).	Danyel Johnson (b) (4)	14 Dec 2020 21:09:16
User opened query 'Per DM CLR: Narrative indicates that the subject received Levaquin, Prednisone and Oxygen at 4 L/min rate. However, there is no corresponding ConMed record that match these information. Please review and update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:41:01
User closed query 'PV query: Please report if there was an identified trigger for the COPD exacerbation (ie. infection, medication noncompliance, etc.).' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:29:12
User closed query 'PV Query: Please add treatment medications to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:29:07
User closed query 'PV Query: Please provide initial signs and symptoms experienced by patient, along with oxygen saturation levels.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:29:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including CXR if performed). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:28:56
Query 'PV query: Please report if there was an identified trigger for the COPD exacerbation (ie. infection, medication noncompliance, etc.).' answered with 'Per review of records none identified ' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:42:23
Query 'PV Query: Please add treatment medications to concomitant medication eCRF.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:42:05

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide initial signs and symptoms experienced by patient, along with oxygen saturation levels.' answered with 'Per records the only symptom reported was shortness of breath' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:41:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including CXR if performed). Please include units and reference ranges if applicable.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:41:31
User entered '76 y/o randomized male who received the first dose of blinded mRNA-1273 or placebo for SARS-CoV-2 vaccination on 8/18/2020 and his second, final dose of study drug, on 09/15/ 2020. Presented to the ER on 10/8/2020 with worsening of shortness of breath per ER records SpO2 was at 75% prior to O2 administration upon admission SpO2 was at 94%. Subject states he was seen by his pulmonologist 10/7/2020 and was diagnosed with a COPD exacerbation the subject was treated with Levaquin, Prednisone, and O2 at 4l. Subject was admitted and treated with Benzonatate 200mg TID prn X7 days, doxycycline 100mg 1 po bid x 7 days, Guaifenesin 600mg bid X 7 days Ipratropium-albuterol 20-100mcg 1 puff qid, Prednisone taper 40mg X3 days , 20mg for 3 days, 10mg for 3 days. COVID testing as well as Influenza A and B testing completed both with negative results. Chest xray completed results within normal limits.' reason for change: New Information	Danyel Johnson (b) (4)	12 Nov 2020 14:41:19
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User opened query 'PV query: Please report if there was an identified trigger for the COPD exacerbation (ie. infection, medication noncompliance, etc.).' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:59:02
User opened query 'PV Query: Please add treatment medications to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:58:40

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide initial signs and symptoms experienced by patient, along with oxygen saturation levels.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:57:43
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including CXR if performed). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:57:01
User entered 'SUBJECT REPORTED TO STAFF THAT HE WAS HOSPITALIZED FROM 08 OCT 2020 THROUGH 09 OCT 2020 FOR LESS THAN 24 HOURS. SUBJECT REPORTED THAT HE HAD LOW OXYGEN LEVELS UPON ADMISSION TO THE HOSPITAL. SUBJECT REPORTS THAT HE WAS GIVEN MEDICATIONS IN THE HOSPITAL AND UPON DISCHARGE, BUT WASN'T SURE OF THE NAMES OF THE MEDICATIONS OR THE DOSES. SUBJECT SIGNED A MEDICAL RECORDS RELEASE FORM DURING OFFICE VISIT. SITE TO REQUEST RECORDS. SUBJECT INSTRUCTED TO FOLLOW UP WITH SITE WITH ANY WORSENING OF CONDITIONS. SITE TO CONTINUE TO MONITOR.	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:54:15

SAE Follow Up #1: Records received and reviewed by site staff. Subject was admitted to the hospital on 08 OCT 2020 at 12:39 AM and discharged on 09 OCT 2020 at 10:49 AM. Subject was hospitalized for greater than 24 hours changing the AE to an SAE. Subject tested negative for Flu A, Flu B, and COVID-19. Subject's exacerbation was treated with nebulized medications, steroids, and antibiotics during hospitalization. Subject stabilized and discharged home with prescriptions for benzonatate, doxycycline, Guaifenesin, Combivent Respimat, and prednisone taper. Subject was not clear on the start date of the prednisone taper, or current dose. Site to request additional records for clarification.' reason for change: New Information

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported to staff that he was hospitalized from 08 OCT 2020 through 09 OCT 2020 for less than 24 hours. Subject reported that he had low oxygen levels upon admission to the hospital. Subject reports that he was given medications in the hospital and upon discharge, but wasn't sure of the names of the medications or the doses. Subject signed a medical records release form during office visit. Site to request records. Subject instructed to follow up with site with any worsening of conditions. Site to continue to monitor.'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 21:54:15
User entered '0'	System	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 13:51:06

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:00:04

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:51:47
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Thank you for the update. Please respond once updated.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:42:53
Query 'Thank you for the update. Please respond once updated.' answered with 'Data has been updated' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 21:17:15
User opened query 'Thank you for the update. Please respond once updated.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:44:08
User closed query 'Per ETRTR: According to SAE "COPD Exacerbation" page, medication was dosed for SAE. Please add Medication dosing details for SAE "COPD Exacerbation" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:44:08
Query 'Per ETRTR: According to SAE "COPD Exacerbation" page, medication was dosed for SAE. Please add Medication dosing details for SAE "COPD Exacerbation" within ConMeds page, thanks.' answered with 'Per subject report medications are unknown site is awaiting records to update data ' (Site from CRA).	Danyel Johnson (b) (4)	22 Oct 2020 20:58:15
User opened query 'Per ETRTR: According to SAE "COPD Exacerbation" page, medication was dosed for SAE. Please add Medication dosing details for SAE "COPD Exacerbation" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 21:42:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:56:06

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:10:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:10:18
Data point term sent to Coder	System	19 Aug 2020 10:58:23
User entered 'Albuterol Sulfate HFA'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered '90'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:57:33
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:57:33
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:01:24
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 10:57:33
User entered 'un Jun 2020'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:57:33
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:57:33
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:03:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 10:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 10:59:20
Data point term sent to Coder	System	19 Aug 2020 10:58:21
User entered 'Carvedilol'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:03:46
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:03:47
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:03:53
User entered '3.125'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:03:54
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:04:02
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, Frequency entered does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:49:41
Query 'Per source, Frequency entered does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:52:42
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:52:32
User entered 'twice daily (BID)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User opened query 'Per source, Frequency entered does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:03:20
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:03
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:04:14
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:04:15
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 10:58:20
User entered 'un UNK 2017'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:04:19
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:04:22
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:04:26
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:58:20
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Nov 2020 13:52:32
User entered '1'	System	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:08:02
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: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:00:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:00:19
Data point term sent to Coder	System	19 Aug 2020 10:59:24
User entered 'Vitamin D3'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 11:59:37
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'Verified and updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 00:05:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:07:51
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM). User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4), (b) (6)	15 Oct 2020 19:07:39
	(b) (4), (b) (6)	29 Sep 2020 10:17:11
	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:04
User entered 'Supplement'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:06
User entered '5000'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 11:59:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:08:13
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'UPdated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 19:14:39
User entered 'IU (IU)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 19:14:32
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:22:26
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:08:17
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:08:22
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:23
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:24
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:08:26
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:08:27
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 10:59:07
User entered 'un UNK 2020'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:08:42
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:43
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:45
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:46
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:02:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:02:21
Data point term sent to Coder	System	19 Aug 2020 11:01:25
User entered 'Duoneb'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered '3'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'mL (mL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:00:31
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:00:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:00:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:00:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:02:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:02:20
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 11:01:25
User entered 'Eliquis'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Atrial Fibrillation'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '5'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, Frequency does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:45
Query 'Per source, Frequency does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	29 Oct 2020 14:42:54
User entered 'twice daily (BID)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	29 Oct 2020 14:42:39
User opened query 'Per source, Frequency does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:14:44
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:12:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:00:59
User entered 'un UNK 2019'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:59
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Oct 2020 14:42:39
User entered '1'	System	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 12:12:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 12:12:33
Data point term sent to Coder	System	19 Aug 2020 11:02:25
User entered 'Finasteride'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Benign prostatic hyperplasion'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '5'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:01:30
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:01:30
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:03:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:03:24
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 11:02:25
User entered 'Gabapentin'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:58:09
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:22:56
User entered 'Neuropathy'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:57
Query 'Per source, dose per administration does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:53:34
User entered '800' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:53:25
User opened query 'Per source, dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:17:51
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:16:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '600'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'three times daily (TID)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2011). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 10:57:38
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2011). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Reviewed and updated per subject report' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:48:17
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:48:00
User entered 'UN UNK 2011' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:48:00
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2011). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:26:09
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:02:00
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:04:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:04:25
Data point term sent to Coder	System	19 Aug 2020 11:03:26
User entered 'Humalog'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Diabetes Type II'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '100'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'units/ml'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:02:36
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:36
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 12:12:33
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 12:12:33
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 11:03:27
User entered 'hydrocodone-acetaminophen'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:58:44
User opened query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:24:31
User entered 'Chronic Pain'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '10/325'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:03:17
User entered 'un Jan 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:03:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:05:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:05:15
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 11:04:27
User entered 'Levothyroxine'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Hypothyroidism'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '100'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:04:17
User entered 'un UNK 2016'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:06:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:06:19
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 11:05:28
User entered 'Montelukast'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Allergic Rhinitis'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '10'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:04:46
User entered 'un May 2020'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:04:46
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:19:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:19:31
Data point term sent to Coder	System	15 Oct 2020 19:18:24
Data point term sent to Coder	System	15 Oct 2020 19:16:18
Coding entries removed.	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:16:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:50:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:50:16
Data point term sent to Coder	System	19 Aug 2020 11:05:30
User entered 'Nitroglycerin'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please update the indication to reflect the type of CHEST PAIN (e.g. cardiac, non-cardiac). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:00:04
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please update the indication to reflect the type of CHEST PAIN (e.g. cardiac, non-cardiac). Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:16:21
User entered 'Angina' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:16:10
User opened query 'Per DM CLR: Please update the indication to reflect the type of CHEST PAIN (e.g. cardiac, non-cardiac). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:24:57
User entered 'Chest Pain'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '.4'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	15 Oct 2020 19:17:23
User entered 'Other (OTHER)' reason for change:	Alyssa-Kay Peay (b) (4)	15 Oct 2020 19:17:23
Data Entry Error	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	19 Aug 2020 11:05:17
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'sublingual'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:05:17
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:07:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:07:16
Data point term sent to Coder	System	19 Aug 2020 11:06:30
User entered 'Ropinirole'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Restless leg syndrome'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'I'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:05:44
User entered 'un UNK 2017'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:41:29
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 Aug 2020 15:41:29
Data point term sent to Coder	System	19 Aug 2020 11:06:31
User entered 'Setraline'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Depression'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, Dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:59:17
Query 'Per source, Dose per administration does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:57:37
User entered '50' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:57:27
User opened query 'Per source, Dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:26:42
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:26:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '25'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:06:23
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:06:23
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:06:23
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:06:23
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:06:23
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:06:23
User entered 'un UNK 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:06:23
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:06:23
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:08:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Aug 2020 11:08:16
Data point term sent to Coder	System	19 Aug 2020 11:07:32
User entered 'Symbicort'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "2 puff." Please provide the actual dose for this medication as there are multiple dosage options for this combination medication. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:00:17
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "2 puff." Please provide the actual dose for this medication as there are multiple dosage options for this combination medication. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 19:29:43
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 19:29:30
User entered '160/4.5' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 19:29:30
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "2 puff." Please provide the actual dose for this medication as there are multiple dosage options for this combination medication. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:15:23
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:15:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:20:15

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:25:36
User entered '2'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 19:29:30
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 19:29:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'puff (PUFF)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Oct 2020 19:20:00
	(b) (4)	
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per CDM: "Dose Unit" field has an option as "Puff". Please consider removing data from this field and update the "Dose Unit" field as "Puff".' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:00:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per CDM: "Dose Unit" field has an option as "Puff". Please consider removing data from this field and update the "Dose Unit" field as "Puff".' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:20:23
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:20:00
User opened query 'Per CDM: "Dose Unit" field has an option as "Puff". Please consider removing data from this field and update the "Dose Unit" field as "Puff".' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:49:31
User entered 'puffs'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:07:24
User entered 'un UNK 2014'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:09:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:09:19
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 11:08:32
User entered 'Tamsulosin'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Benign prostatic hyperplasia'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '.4'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:07:56
User entered 'un UNK 2016'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:56
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:09:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:09:20
Data point term sent to Coder	System	19 Aug 2020 11:08:33
User entered 'Trazodone'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '50'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 11:08:22
User entered 'un UNK 2019'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:08:22
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 06:45:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 06:45:02
Data point term sent to Coder	System	02 Nov 2020 18:04:29
User entered 'Atorvastatin'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:03:43

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 10:58:12
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Reviewed and updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:50:20
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:13
User entered 'Hyperlipidemia'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:03:43

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '80'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'UN UNK 2012'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:03:43

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:03:43

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 18:03:43

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Dec 2020 16:53:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 16:53:51
Data point term sent to Coder Coding entries removed.	System Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:25 14 Dec 2020 21:13:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 06:54:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 06:54:09
Data point term sent to Coder User entered 'Meloxicam'	System Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:07:33 02 Nov 2020 18:06:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 10:58:17
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:10
User entered 'OSTEOARTHRITIS Bilateral extremities' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:00
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:23
User entered 'Osteoarthritis'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:06:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '15'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'UN UNK 2017'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:06:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:06:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 18:06:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:14:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:14:14
Data point term sent to Coder	System	02 Nov 2020 18:10:39
User entered 'Benzonatate'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:49
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:47
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:51
User entered '200'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:54
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:55
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:58
User entered 'three times daily (TID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:02
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:06
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:08
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:12
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:14
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:16
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:00:55
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:18
User entered '16 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:00:55
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:53:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:05:47
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'Data entry error' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:44
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:34
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:34
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:44
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User entered '3'	System	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User entered '1'	System	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User entered '804 (804)'	System	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 12:52:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 12:52:17
Data point term sent to Coder	System	02 Nov 2020 18:18:49
User entered 'Doxycycline'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:30
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:31
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:36
User entered '100'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:37
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:39
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:40
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:44
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:45
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:48
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:51
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:54
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:02:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:55
User entered '16 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:02:04
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:22:16
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:05:52
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'data entry error' (Site from DM).	Danyel Johnson (b) (4)	14 Dec 2020 21:14:16
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 21:14:06
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 08:27:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 17:15:57
	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User entered '2'	System	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User entered '1'	System	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User entered '804 (804)'	System	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Dec 2020 20:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:35:48
Data point term sent to Coder	System	14 Dec 2020 21:15:28
Coding entries removed.	Danyel Johnson (b) (4)	14 Dec 2020 21:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:32:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:32:21
Data point term sent to Coder	System	02 Nov 2020 18:19:50
User entered 'Guaifenesin'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:05
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:24:16
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Dec 2020 21:14:59
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 21:14:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:07
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:10
User entered '600'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:11
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:13
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:16
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:18
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:19
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:22
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:24
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:28
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:30
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:02:35
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:33
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:02:35
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:02:21
User entered '16 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 16:02:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:22:32
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:05:56
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'Data entry error' (Site from DM).	Danyel Johnson (b) (4)	14 Dec 2020 21:15:13
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 21:14:59
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 08:28:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 17:16:34
	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User entered '2'	System	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User entered '1'	System	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User entered '804 (804)'	System	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User closed query 'please confirm levaquin should be entered.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 17:52:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
Query 'please confirm levaquin should be entered.' answered with 'Based on review of records and with subject Levaquin was never started Levaquin' (Site from CRA).	Danyel Johnson (b) (4)	19 Feb 2021 17:23:51
User opened query 'please confirm levaquin should be entered.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 15:31:32
User closed query 'per SAE note in EDC, subject took LEVAQUIN, PREDNISONE, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 15:31:32
Query 'per SAE note in EDC, subject took LEVAQUIN, PREDNISONE, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. Please confirm and update.' answered with 'Reviewed and updated' (Site from CRA).	Danyel Johnson (b) (4)	09 Feb 2021 15:40:26
User opened query 'per SAE note in EDC, subject took LEVAQUIN, PREDNISONE, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 19:26:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT RESPIMAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 05:21:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 05:21:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

2489 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Nov 2020 18:23:58
User entered 'Combivent Respimat (Ipratropium Albuterol)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:23:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:41
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:43
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:45
User entered 'I'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:47
User entered 'puff (PUFF)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:49
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:51
User entered 'four times daily (QID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:53
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:55
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:59
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:01
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 09:14:04
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Subject continued medication as treatment for COPD' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:01:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 20:02:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:02
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:05
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:22:40
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:06:02
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.	Danyel Johnson (b) (4)	14 Dec 2020 21:15:40
' answered with 'Data entry error' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Dec 2020 21:15:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 21:15:29
	(b) (4)	
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:28:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:06
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:23:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:48
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:57:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:57:47
Data point term sent to Coder	System	09 Feb 2021 15:57:30
User entered 'Prednisone'	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:27
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'COPD Exacerbation'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:30
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '40'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'mg (mg)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:33
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'once daily (QD)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (ORAL)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '08 Oct 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '10 Oct 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
User entered '1'	System	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
User entered '1'	System	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
User entered '804 (804)'	System	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:49
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:58:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:58:47
Data point term sent to Coder	System	09 Feb 2021 15:58:30
User entered 'Prednisone'	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'COPD Exacerbation'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '20'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'mg (mg)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:13
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'once daily (QD)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:15
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (ORAL)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:20
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:23
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '11 Oct 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '13 Oct 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
User entered '1'	System	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
User entered '1'	System	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
User entered '804 (804)'	System	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:14
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:49
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 16:17:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 16:17:56
Data point term sent to Coder	System	09 Feb 2021 16:01:02
User entered 'Prednisone'	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:15
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'COPD Exacerbation'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '10'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'mg (mg)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'once daily (QD)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:33
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (ORAL)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '14 Oct 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:33:25
User closed query 'Please review source and revise if needed. Source states that the end date for this Con Med is 14Oct2020.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:33:04
Query 'Please review source and revise if needed. Source states that the end date for this Con Med is 14Oct2020.' answered with 'Corrected per source' (Site from CRA).	Danyel Johnson (b) (4)	21 Apr 2021 19:27:44
Signature has been broken.	Danyel Johnson (b) (4)	21 Apr 2021 19:27:14
User entered '14 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	21 Apr 2021 19:27:14
User opened query 'Please review source and revise if needed. Source states that the end date for this Con Med is 14Oct2020.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:57:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '16 Oct 2020'	Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:57:20
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User entered '1'	System	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User entered '1'	System	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User entered '804 (804)'	System	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User closed query 'Please add to Con Med Log in Source so data can be verified.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:56:41
Query 'Please add to Con Med Log in Source so data can be verified.' answered with 'Added per review' (Site from CRA).	Danyel Johnson (b) (4)	21 Apr 2021 19:46:58
User opened query 'Please add to Con Med Log in Source so data can be verified.' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	21 Apr 2021 19:41:37
	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 09:00:27
	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	30 Mar 2021 09:00:27
User entered 'Oxygen'	(b) (4)	
	System	29 Mar 2021 18:50:08
	Danyel Johnson (b) (4)	29 Mar 2021 18:49:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'COPD exacerbation'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '0.004'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'mL (mL)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'as needed (PRN)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '08 Oct 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '08 Oct 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
User entered empty.	System	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
User entered empty.	System	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
User entered empty.	System	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:00:04

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:52
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Nov 2020 14:43:24

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered '08 Oct 2020'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Chest X-Ray(WNL)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered empty.	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered '08 Oct 2020'	Danyel Johnson (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'COVID 19 Test (negative)'	Danyel Johnson (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered empty.	Danyel Johnson (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered '08 Oct 2020'	Danyel Johnson (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Influenza A and B testing (Negative)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered empty.	Danyel Johnson (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'USA-US100-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered	System	14 Oct 2020 13:41:15
'USA-US100-2020-MRNA-1273-P301000006'		

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered '14/Oct/2020 09:41'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:04

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.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered	System	14 Oct 2020 13:41:15
'USA-US100-2020-MRNA-1273-P301000006'		

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:04:07
User entered '13/Nov/2020 14:29'	System	13 Nov 2020 14:29:39

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:04

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.

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:50:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:04:04
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 14:29:39

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'USA-US100-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:46:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '10/Feb/2021 10:50'	(b) (4) System	10 Feb 2021 15:50:38

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:04

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:46:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 15:50:38