

US3822015 (Prod: Tryon Medical Partners, PLLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:22:22

All time stamps listed in this document are displayed in GMT

US3822015

Form: Participant Creation

Generated On: 26 Nov 2020 11:22:22

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

Date of Birth (MMM yyyy)	(b) (6) 1937
Age	83
Age Units	YEARS
Age (Derived)	83
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

Date of Informed Consent (<i>dd MMM yyyy</i>)	05 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:22:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:22:22

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

Condition	HYPOGONADISM
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

Condition	DEPRESSIVE DISORDER
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

Condition	PERIPHERAL NERVE DISEASE
Start date (dd MMM yyyy)	UN NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

Condition	VENTRICULAR PREMATURE BEATS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

Condition	HYPERCOAGULABILITY STATE
Start date (dd MMM yyyy)	27 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

Condition	TRICUSPID VALVE REGURGITATION
Start date (dd MMM yyyy)	03 DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

Condition	MITRAL VALVE REGURGITATION
Start date (dd MMM yyyy)	03 DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

Condition	AORTIC VALVE REGURGITATION
Start date (dd MMM yyyy)	27 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

Condition	PULMONIC VALVE REGURGITATION
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

Condition	BIOTRINK PACEMAKER INSERTION
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

Condition	SINUS NODE DYSFUNCTION
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

Condition	CHRONOTROPIC INCOMPETENCE
Start date (dd MMM yyyy)	01 APR 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	16 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

Condition	BENIGN PROSTAIC HYPERPLASIA
Start date (dd MMM yyyy)	27 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

Condition	HEART MURMUR
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

Condition	SENILE PURPURA LEFT ARM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	05 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:40 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 12:40
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	189.6 lb
BMI (<i>xxx.x</i>)	28.88886 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
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)	

US3822015

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility True

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 184623

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:22

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	05 AUG 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 12:40
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	05 AUG 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 13:43
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3822015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

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)	05 AUG 2020
What was the treatment time? (00:00-23:59)	13:05 (24 HR)
Treatment Date and Time (derived)	05 AUG 2020 13:05
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

05 AUG 2020

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

12:46 (24 HR)

Collection date and time (derived)

05 AUG 2020 12:46

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:22:22

Collection date (<i>dd MMM yyyy</i>)			05 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:57	05 AUG 2020 12:57
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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 98.8 °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):

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

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

PC Time Stamp 05 AUG 2020 13:35

PC Open Date & Time 05 AUG 2020 13:25

PC Close Date & Time 05 AUG 2020 15:55

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

97.1 °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

06 AUG 2020 07:20

PC Open Date & Time

05 AUG 2020 16:50

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

07 AUG 2020 06:32

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:53

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

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

08 AUG 2020 21:55

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 22:10

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

10 AUG 2020 22:10

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

11 AUG 2020 22:04

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

05 AUG 2020 13:32

PC Open Date & Time

05 AUG 2020 13:25

PC Close Date & Time

05 AUG 2020 15:55

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

06 AUG 2020 07:21

PC Open Date & Time

05 AUG 2020 16:50

PC Close Date & Time

06 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

07 AUG 2020 06:33

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

07 AUG 2020 12:54

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

08 AUG 2020 21:56

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

09 AUG 2020 22:11

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

10 AUG 2020 22:11

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

11 AUG 2020 22:06

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 13:38
PC Open Date & Time	05 AUG 2020 13:25
PC Close Date & Time	05 AUG 2020 15:55

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 07:22
PC Open Date & Time	05 AUG 2020 16:50
PC Close Date & Time	06 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	07 AUG 2020 06:34
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	07 AUG 2020 12:55
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	08 AUG 2020 21:57
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	09 AUG 2020 22:12
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	10 AUG 2020 22:12
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	11 AUG 2020 22:07
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3822015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

Was Contact Attempted?

Yes ☒

No ☐

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

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 12:17
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3822015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

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.

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:47 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 11:47

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

US3822015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	3 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:11 (24 HR)
Collection date and time (derived)	3 SEP 2020 11:11

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:22:22

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:26	3 SEP 2020 11:26
Nasopharyngeal Swab 2	No		

US3822015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:10

PC Open Date & Time

03 SEP 2020 12:07

PC Close Date & Time

03 SEP 2020 14:37

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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 97.9 °F

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

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

PC Time Stamp	03 SEP 2020 21:33
PC Open Date & Time	03 SEP 2020 15:32
PC Close Date & Time	04 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 21:48

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 22:08

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:58

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

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.

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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

09 SEP 2020 20:21

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

03 SEP 2020 12:11

PC Open Date & Time

03 SEP 2020 12:07

PC Close Date & Time

03 SEP 2020 14:37

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:34

PC Open Date & Time

03 SEP 2020 15:32

PC Close Date & Time

04 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 21:49

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

05 SEP 2020 22:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 21:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 22:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 20:59

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 20:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 12:12
PC Open Date & Time	03 SEP 2020 12:07
PC Close Date & Time	03 SEP 2020 14:37

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 21:35
PC Open Date & Time	03 SEP 2020 15:32
PC Close Date & Time	04 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	04 SEP 2020 21:51
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	05 SEP 2020 22:17
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	06 SEP 2020 21:58
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	07 SEP 2020 22:10
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	08 SEP 2020 21:00
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

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 ☒

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

Yes ☐	
PC Time stamp	09 SEP 2020 20:22
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3822015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	1 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:43 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 11:43
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3822015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	1 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:51 (24 HR)
Collection date and time (derived)	1 OCT 2020 11:51

US3822015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 18:00:29

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

12 OCT 2020 06:37:36

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 06:09:17

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 06:24:22

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 06:30:51

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 06:40:07

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 06:44:18
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐ Yes ☐

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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12 APR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

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15 APR 2022 00:01

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19 APR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

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22 APR 2022 00:01

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26 APR 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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31 MAY 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

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03 JUN 2022 00:01

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07 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

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10 JUN 2022 00:01

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14 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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21 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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°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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

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12 JUL 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

DAY 796

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822015

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:22:22

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3822015

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:22:22

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3822015

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:22:22

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

AEID	USA-US126-2020-MRNA-1273-P30 1000002
Adverse event	HEART FAILURE
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	12 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	12 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	355 of 2310

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

PATIENT HAD PLANNED
OUTPATIENT ABLATION FOR
PERMANENT ATRIAL
FIBRILLATION ON 9SEP20. HE
FELT WELL BUT DURING THE
NIGHT HE DEVELOPED
SHORTNESS OF BREATH,
CHEST DISCOMFORT AND WAS
FOUND TO BE HYPOXIC. A
CHEST X-RAY FOUND NEW
MILD RIGHT PLEURAL
EFFUSION. HE WAS GIVEN
OXYGEN. AN ECHO WAS
PERFORMED WHICH SHOWED
A DECREASED EJECTION
FRACTION AS COMPARED TO
PREVIOUS TEST. HE IS
CONTINUING TO RECEIVE
OXYGEN AND IS WORKING
WITH INCENTIVE SPIROMETER.
HE IS ABLE TO GET UP AND
MOVE AROUND WITH
ASSISTANCE. SYMPTOMS
RESOLVING WITH OXYGEN.

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

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

AEID	
Adverse event	RIGHT PLEURAL EFFUSION
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

AEID	
Adverse event	BILATERAL EDEMA, LEGS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	12 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	360 of 2310

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:22:22

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

Yes ☒

No ☐

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

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	ELIQUIS
Prophylaxis	Yes ☒ No ☐
Indication	CARDIAC HEALTH
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 ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	FLUTICASONE PROPIONATE
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
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 ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☒
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	PERIPHERAL NERVE DISEASE
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	HYPTERTENSION
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 ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	METROPROLOL SUCCINATE ER
Prophylaxis	Yes ☐ No ☒
Indication	VENTRICULAR PREMATURE BEATS
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 ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	0.4
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 ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	TESTOSTERONE CYPIONATE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOGONADISM
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	TYLENOL
Prophylaxis	Yes ☒ No ☐
Indication	UNKNOWN
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	INFLUENZA
Prophylaxis	Yes ☒ No ☐
Indication	VACCINE
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 ☐ Intramuscular ☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2019
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	PNEUMOCOCCAL PCV 13
Prophylaxis	Yes ☒ No ☐
Indication	VACCINE
Dose per administration	UNK
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 ☐ Intramuscular ☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		4 MAY 2016
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		4 MAY 2016
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	PNEUMOCOCCAL PPV 23
Prophylaxis	Yes ☒ No ☐
Indication	VACCINE
Dose per administration	UNK
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 ☐ Intramuscular ☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		7 APR 2015
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		7 APR 2015
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	ZOSTER
Prophylaxis	Yes ☒ No ☐
Indication	VACCINE
Dose per administration	UNK
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 ☐ Intramuscular ☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 2018	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		UN OCT 2018
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	OXYGEN
Prophylaxis	Yes ☐ No ☒
Indication	HEART FAILURE
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	LITERS
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	CONTINUOUS PUMP
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	TYLENOL PM
Prophylaxis	Yes ☐ No ☒
Indication	OBSTRUCTIVE SLEEP APNEA SYNDROME
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	CARDIAC ABLIATION
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☒ No ☐
Indication	GI PROPHYAXIS
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 ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

Name of Medication	LASIX
Prophylaxis	Yes ☐ No ☒
Indication	BILATERAL EDEMA
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
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 ☐ Intramuscular ☐

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:22:22

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:22:22

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 SEP 2020	CT ANGIOGRAPHY CORONARY ARTERY SCAN	Diagnostic	
11 SEP 2020	CT CORONARY CHEST NONCARDIAC WITH CONTRAST	Diagnostic	
10 SEP 2020	CHEST X-RAY 1 VIEW	Diagnostic	
12 SEP 2020	CHEST X-RAY 2 VIEWS	Diagnostic	
09 SEP 2020	CARDIAC ABLATION	Medical History	
10 SEP 2020	ECHOCARDIOGRAM	Adverse Event	
11 SEP 2020	INCENTIVE SPIROMETER	Other	PROPHYLAXIS

US3822015

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:22:22

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

US3822015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:22:22

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 ☐

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/SEP/2020 14:53
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

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/SEP/2020 11:31
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

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/SEP/2020 10:28
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

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	06/OCT/2020 14:05
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

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/OCT/2020 15:33
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

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	13/OCT/2020 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/OCT/2020 18:55
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

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 11:22:22

SAEID	USA-US126-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/NOV/2020 20:52
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

US3822015 (Prod: Tryon Medical Partners, PLLC)

US3822015

Form: Participant Creation

Generated On: 26 Nov 2020 11:22:22

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:45:57
User entered 'US3822015'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:44:51

US3822015

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:24
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:34

US3822015

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:24
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:44:52

US3822015

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:24
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:34

US3822015

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	05 Aug 2020 17:08:34

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered (b) (6) 1937'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:44:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '83'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53
	(b) (4)	

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '83'	System	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered 'Male (M)'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53
	(b) (4)	

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '1'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53
	(b) (4)	

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53
	(b) (4)	

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:22:22

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:07:59
User entered '0'	Kelly Woodell (b) (4)	05 Aug 2020 17:08:53

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered '05 Aug 2020'	Kelly Woodell (b) (4)	05 Aug 2020 17:09:10
	(b) (4)	

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered '2020'	System	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Sep 2020 15:49:14
User closed query 'Please document protocol version in source document, currently the ICF Version is documented. ' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 15:49:09
Query 'Please document protocol version in source document, currently the ICF Version is documented. ' answered with 'date updated in source' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:48:44
User opened query 'Please document protocol version in source document, currently the ICF Version is documented. ' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 19:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	02 Sep 2020 19:14:24
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered 'Amendment 1 (1)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:10

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:08:30
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:44:52

US3822015

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:22:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 17:09:16

US3822015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:18:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:16

US3822015

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:22:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User closed query 'If applicable, please add Purpura on left arm and skin lesion on right arm as noted at Screening Physical.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:17:01
Query 'If applicable, please add Purpura on left arm and skin lesion on right arm as noted at Screening Physical.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:09:03
User opened query 'If applicable, please add Purpura on left arm and skin lesion on right arm as noted at Screening Physical.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 14:45:03
User closed query 'Please verify, if the following conditions listed in the source document should be added to medical history: Hypercoagulability State and Tricuspid/Mitral/Aortic/Pulmonic Valve Regurgitation. ' (Site from CRA).	(b) (4), (b) (6)	08 Sep 2020 16:28:12
Query 'Please verify, if the following conditions listed in the source document should be added to medical history: Hypercoagulability State and Tricuspid/Mitral/Aortic/Pulmonic Valve Regurgitation. ' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	07 Sep 2020 21:43:44
User opened query 'Please verify, if the following conditions listed in the source document should be added to medical history: Hypercoagulability State and Tricuspid/Mitral/Aortic/Pulmonic Valve Regurgitation. ' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 19:23:24
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:18:12
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:20:05

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:23
Data point term sent to Coder	System	05 Nov 2020 16:17:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:03:56
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:22:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:22:12
Data point term sent to Coder	System	16 Aug 2020 13:21:49
User entered 'Hypogonadism'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'UN UNK 2018'	Kelly Woodell (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:03:58
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Jan 2018'	System	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:21:41

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depressive disorder - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:33:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:33:24
Data point term sent to Coder	System	05 Nov 2020 16:17:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depressive disorder - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 13:24:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 13:24:13
Data point term sent to Coder	System	16 Aug 2020 13:22:49
User entered 'Depressive Disorder'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Un Jun 2020'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Jun 2020'	System	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2020'	System	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:22:30

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:33:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	05 Nov 2020 16:33:25
Data point term sent to Coder	System	05 Nov 2020 16:17:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 13:24:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	16 Aug 2020 13:24:13
Data point term sent to Coder	System	16 Aug 2020 13:23:50
User entered 'Insomnia'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:58
	(b) (4)	

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Un Sep 2019'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Sep 2019'	System	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:22:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:33:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:33:24
Data point term sent to Coder	System	05 Nov 2020 16:17:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:27:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:27:14
Data point term sent to Coder	System	16 Aug 2020 13:25:50
User entered 'Obstructive sleep apnea'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'UN Sep 2019'	Kelly Woodell (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Sep 2019'	System	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:24:58

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
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)	05 Nov 2020 16:18:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:29
Data point term sent to Coder	System	05 Nov 2020 16:17:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:28
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
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)	16 Aug 2020 13:27:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:27:14
Data point term sent to Coder	System	16 Aug 2020 13:25:50
User entered 'Restless Leg Syndrome'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Un Nov 2018'	Kelly Woodell (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Nov 2018'	System	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:25:34

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral nerve disorder NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:26
Data point term sent to Coder	System	05 Nov 2020 16:17:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral nerve disorder NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:15:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:15:20
Data point term sent to Coder	System	16 Aug 2020 13:26:50
User entered 'Peripheral Nerve Disease'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Un Nov 2018'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:05

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:26:05

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Nov 2018'	System	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:26:05

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
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)	05 Nov 2020 16:18:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:25
Data point term sent to Coder	System	05 Nov 2020 16:17:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	02 Oct 2020 11:21:53
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Krishna Shah Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4)	28 Sep 2020 21:25:04
' answered with 'updated ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	28 Sep 2020 09:25:56
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
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)	16 Aug 2020 13:28:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:28:14
v6.020 DTW (1102)		

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	16 Aug 2020 13:26:51
User entered 'Hypertension'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:38
	(b) (4)	

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Un UNK 2018'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Jan 2018'	System	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:26:38

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

Condition

Audit	User	Time (GMT)
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)	05 Nov 2020 16:18:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:22
Data point term sent to Coder	System	05 Nov 2020 16:17:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	02 Oct 2020 11:21:57
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Krishna Shah Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4)	28 Sep 2020 21:25:15
' answered with 'updated ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	28 Sep 2020 09:26:07
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
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)	16 Aug 2020 13:29:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:29:15
Data point term sent to Coder	System	16 Aug 2020 13:27:51

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User entered 'Atrial Fibrillation'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Un UNK 2018'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:17

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:17

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:27:17

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Jan 2018'	System	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	16 Aug 2020 13:27:17

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:27:17

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular ectopic beats - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:23
Data point term sent to Coder	System	05 Nov 2020 16:17:39
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular ectopic beats - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 07:53:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 07:53:20
Data point term sent to Coder	System	16 Aug 2020 13:27:51
User entered 'Ventricular premature beats'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:27:43

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'UN UNK 2019'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:43

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:43

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Jan 2019'	System	16 Aug 2020 13:27:43

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	16 Aug 2020 13:27:43

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Hypercoagulation, LLT: Hypercoagulability - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:24
Data point term sent to Coder	System	05 Nov 2020 16:17:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:29
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Hypercoagulation, LLT: Hypercoagulability - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 05:31:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 05:31:47
Data point term sent to Coder	System	07 Sep 2020 21:44:51
User entered 'Hypercoagulability state'	Kelly Woodell (b) (4)	07 Sep 2020 21:44:19

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '27 Dec 2019'	Kelly Woodell (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:44:19

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 21:44:19

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Dec 2019'	System	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:44:19

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Tricuspid valvular disorders, PT: Tricuspid valve incompetence, LLT: Tricuspid regurgitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:25
Data point term sent to Coder	System	05 Nov 2020 16:17:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Tricuspid valvular disorders, PT: Tricuspid valve incompetence, LLT: Tricuspid regurgitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:46:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 21:46:33
Data point term sent to Coder	System	07 Sep 2020 21:45:52
User entered 'Tricuspid valve regurgitation'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '03 Dec 2018'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Dec 2018'	System	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:45:13

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:33:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:33:24
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 21:46:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 21:46:33
Data point term sent to Coder	System	07 Sep 2020 21:45:52
User entered 'Mitral valve regurgitation'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '03 Dec 2018'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Dec 2018'	System	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:45:30

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Aortic valvular disorders, PT: Aortic valve incompetence, LLT: Aortic regurgitation - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:21
Data point term sent to Coder	System	05 Nov 2020 16:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:30
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Aortic valvular disorders, PT: Aortic valve incompetence, LLT: Aortic regurgitation - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 21:46:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 21:46:32
Data point term sent to Coder	System	07 Sep 2020 21:45:51
User entered 'aortic valve regurgitation'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '27 Dec 2019'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Dec 2019'	System	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:45:44

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Pulmonary valvular disorders, PT: Pulmonary valve incompetence, LLT: Pulmonary valve regurgitation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:21
Data point term sent to Coder	System	05 Nov 2020 16:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Pulmonary valvular disorders, PT: Pulmonary valve incompetence, LLT: Pulmonary valve regurgitation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 06:59:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 06:59:14
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
Data point term sent to Coder	System	07 Sep 2020 21:46:53
User entered 'pulmonic valve regurgitation'	Kelly Woodell (b) (4) (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '01 Apr 2019'	Kelly Woodell (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered empty.	Kelly Woodell (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:04:03
User entered '0'	Kelly Woodell (b) (4)	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Apr 2019'	System	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	07 Sep 2020 21:46:08

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:26
Data point term sent to Coder	System	05 Nov 2020 16:17:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:38:42
User closed query 'Unable to locate this data point in source, kindly provide. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:38:35
Query 'Unable to locate this data point in source, kindly provide. Thank you.' answered with 'added to CRIO' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:39:05
User opened query 'Unable to locate this data point in source, kindly provide. Thank you.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:39:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:14:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:14:26
Data point term sent to Coder	System	22 Oct 2020 18:17:01
User entered 'Biotrink pacemaker insertion'	Kelly Woodell (b) (4) (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:38:45
User entered '01 Apr 2019'	Kelly Woodell (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:38:48
User entered '0'	Kelly Woodell (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:38:52
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:38:56
User entered empty.	Kelly Woodell (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:39:00
User entered '0'	Kelly Woodell (b) (4)	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Apr 2019'	System	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	22 Oct 2020 18:16:58

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus node dysfunction, LLT: Sinus node dysfunction - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:28
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:42:32
User closed query 'Unable to locate this data point in source, kindly provide. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:42:29
Query 'Unable to locate this data point in source, kindly provide. Thank you.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:40:40
User opened query 'Unable to locate this data point in source, kindly provide. Thank you.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:39:33
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus node dysfunction, LLT: Sinus node dysfunction - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 18:29:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 18:29:20
Data point term sent to Coder	System	22 Oct 2020 18:18:02
User entered 'sinus node dysfunction'	Kelly Woodell (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CRIO Start Date is 06FEB2019. Please review and reconcile as applicable.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:47:23
Query 'Per CRIO Start Date is 06FEB2019. Please review and reconcile as applicable.' answered with 'Please review CRIO again. date listed is correct. ' (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 22:43:23
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:17:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User opened query 'Per CRIO Start Date is 06FEB2019. Please review and reconcile as applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:44:55
User entered '01 Apr 2019'	Kelly Woodell (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:42:37
User entered '0'	Kelly Woodell (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:42:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:42:43
User entered empty.	Kelly Woodell (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:42:46
User entered '0'	Kelly Woodell (b) (4)	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Apr 2019'	System	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	22 Oct 2020 18:17:35

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per Medical Records dated 2015, please confirm if this is the same as Pulmonic Valve Regurgitation.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:50:29
Query 'Per Medical Records dated 2015, please confirm if this is the same as Pulmonic Valve Regurgitation.' answered with 'This was split from pulmonic valve regurgitation per previous query. Please clarify what is needed. ' (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 22:45:10
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Chronotropic incompetence, LLT: Chronotropic incompetence - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:22
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:59:14
User opened query 'Per Medical Records dated 2015, please confirm if this is the same as Pulmonic Valve Regurgitation.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:59:09
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Chronotropic incompetence, LLT: Chronotropic incompetence - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 22:21:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 22:21:26
Data point term sent to Coder	System	22 Oct 2020 18:20:05
User entered 'chronotropic incompetence'	Kelly Woodell (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:59:16
User entered '01 Apr 2019'	Kelly Woodell (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:59:19
User entered '0'	Kelly Woodell (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:59:23
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:59:30
User entered empty.	Kelly Woodell (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:59:27
User entered '0'	Kelly Woodell (b) (4)	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Apr 2019'	System	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2019'	System	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	22 Oct 2020 18:19:22

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
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)	05 Nov 2020 16:33:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:33:25
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:37
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)	05 Nov 2020 00:36:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 00:36:34
Data point term sent to Coder	System	05 Nov 2020 00:35:53
User entered 'allergic rhinitis'	Kelly Woodell (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:49
User closed query 'Per 2015 Medical Records, onset includes day and month of 16NOV2018. Please reconcile and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:50:43
Query 'Per 2015 Medical Records, onset includes day and month of 16NOV2018. Please reconcile and update as applicable.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:47:54
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:47:48
User entered '16 Nov 2018' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:47:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User opened query 'Per 2015 Medical Records, onset includes day and month of 16NOV2018. Please reconcile and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:01:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:40
User entered 'un UNK 2018'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:43
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:45
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:48
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:50
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered 'Nov 2018'	System	06 Nov 2020 22:47:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Jan 2018'	System	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 00:35:26

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
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)	05 Nov 2020 16:18:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:28
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:03:25
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)	05 Nov 2020 05:23:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:23:39
Data point term sent to Coder	System	05 Nov 2020 00:37:56
User entered 'Benign prostaic hyperplasia'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:51:10
User closed query 'Per 2015 Medical History_Start Date of 27NOV2018 is included. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:51:04
Query 'Per 2015 Medical History_Start Date of 27NOV2018 is included. Please reconcile and update if applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 22:48:19
DataPoint Un-verified.	(b) (4)	06 Nov 2020 22:48:14
User entered '27 Nov 2018' reason for change: Data Entry Error	Krishna Shah (b) (4)	06 Nov 2020 22:48:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User opened query 'Per 2015 Medical History_Start Date of 27NOV2018 is included. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:04:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:03:28
User entered 'un UNK 2018'	Kelly Woodell (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:03:34
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:03:36
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:03:42
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:03:40
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered 'Nov 2018'	System	06 Nov 2020 22:48:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Jan 2018'	System	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '2018'	System	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 00:37:45

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 16:18:20
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:25
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 01:21:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 01:21:32
Data point term sent to Coder	System	05 Nov 2020 01:20:24
User entered 'Heart murmur'	Kelly Woodell (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:27
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:30
User entered '1'	Kelly Woodell (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:33
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:37
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:05:40
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:20:19

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin vascular abnormalities, HLT: Purpura and related conditions, PT: Purpura senile, LLT: Purpura senile - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:18:21
	(b) (4), (b) (6)	05 Nov 2020 16:17:49
Query 'Unable to locate in Medical History, please confirm if located in source and reconcile if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:17:47
Data point term sent to Coder	System	05 Nov 2020 16:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
Data point term sent to Coder	System	05 Nov 2020 16:15:32
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User opened query 'Unable to locate in Medical History, please confirm if located in source and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:14:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin vascular abnormalities, HLT: Purpura and related conditions, PT: Purpura senile, LLT: Purpura senile - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:50:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:50:37
Data point term sent to Coder	System	05 Nov 2020 01:20:24
User entered 'Senile purpura left arm'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:17:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:17:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '1'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:17:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:17:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:17:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered '0'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:17:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 16:15:25
User entered empty.	System	05 Nov 2020 01:19:39

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:41
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '12:40'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:40'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '68' in	Kelly Woodell (b) (4)	16 Aug 2020 13:28:41
DataPoint set to visible.	(b) (4) System	05 Aug 2020 17:09:16

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '189.6' lb	Kelly Woodell (b) (4)	16 Aug 2020 13:28:41
DataPoint set to visible.	(b) (4) System	05 Aug 2020 17:09:16

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '28.88886'	System	16 Sep 2020 23:44:06
User entered '28.9'	System	16 Aug 2020 13:28:41
DataPoint set to visible.	System	05 Aug 2020 17:09:16

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	16 Aug 2020 13:28:41
DataPoint set to visible.	System	05 Aug 2020 17:09:16

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:25
DataPoint Un-verified.	Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
User entered missing code ND - Not Done; reason for	(b) (4)	16 Sep 2020 22:49:17
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '98.8' F	Kelly Woodell (b) (4)	16 Aug 2020 13:28:41
	(b) (4)	

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered 'Oral (Oral)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:25
DataPoint Un-verified.	Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
User entered missing code ND - Not Done; reason for	(b) (4)	16 Sep 2020 22:49:17
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '68'	Kelly Woodell (b) (4)	16 Aug 2020 13:28:41
	(b) (4)	

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:25
DataPoint Un-verified.	Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
User entered missing code ND - Not Done; reason for	(b) (4)	16 Sep 2020 22:49:17
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '18'	Kelly Woodell (b) (4)	16 Aug 2020 13:28:41
	(b) (4)	

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:25
DataPoint Un-verified.	Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
User entered missing code ND - Not Done; reason for	(b) (4)	16 Sep 2020 22:49:17
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '128'	Kelly Woodell (b) (4)	16 Aug 2020 13:28:41
	(b) (4)	

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:25
DataPoint Un-verified.	Kelly Woodell (b) (4)	16 Sep 2020 22:49:17
User entered missing code ND - Not Done; reason for	(b) (4)	16 Sep 2020 22:49:17
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:43
User entered '76'	Kelly Woodell (b) (4)	16 Aug 2020 13:28:41
	(b) (4)	

US3822015

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 13:28:41

US3822015

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:57
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:28:50

US3822015

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 12:01:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		03 Sep 2020 15:57:50
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:25:57
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:28:50

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered 'No (N)'	Kelly Woodell (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered '1'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered '0'	Kelly Woodell (b) (4)	16 Aug 2020 13:29:29
	(b) (4)	

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:22:22

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:48
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:29:29

US3822015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:56
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 17:09:53

US3822015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:56
User entered '05 Aug 2020'	Kelly Woodell (b) (4)	05 Aug 2020 17:09:53
	(b) (4)	

US3822015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:29:56
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:09:53

US3822015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	05 Aug 2020 17:09:53

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:44:56

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:16:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:16:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 16:44:56
User entered '184623' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:44:56

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:44:56

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:10:43

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:10:43

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:10:43

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:10:43

US3822015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:22:22

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:30:57
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:10:43

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:22

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:43
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Oct 2020 19:08:45
User entered missing code ND - Not Done; reason for	(b) (4)	28 Oct 2020 19:08:45
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:00
User entered '68' in	Kelly Woodell (b) (4)	16 Aug 2020 13:33:13
	(b) (4)	

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:22

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:43
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Oct 2020 19:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:02
User entered '189.6' lb	Kelly Woodell (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:22

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:43
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Oct 2020 19:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:00
User entered '68' in	Kelly Woodell (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:22

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:43
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Oct 2020 19:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:02
User entered '189.6' lb	Kelly Woodell (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered '12:40'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:40'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered '98.8' F	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered 'Oral (Oral)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered '68'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered '18'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered '128'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
User entered '76'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:22

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:43
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Oct 2020 19:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:00
User entered '68' in	Kelly Woodell (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:22:22

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:31:43
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Oct 2020 19:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:02
User entered '189.6' lb	Kelly Woodell (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:05
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:06
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 19:33:39
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).		16 Aug 2020 13:33:13
User entered '13:43'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:43'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Sep 2020 15:49:54
User closed query 'Please verify, per source document value is 98.9. ' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 15:49:51
Query 'Please verify, per source document value is 98.9. ' answered with 'corrected' (Site from CRA).	Kelly Woodell (b) (4)	17 Sep 2020 00:28:54
DataPoint Un-verified.	(b) (4)	
	Kelly Woodell (b) (4)	17 Sep 2020 00:28:39
	(b) (4)	
User entered '98.9' F reason for change: Data Entry Error	Kelly Woodell (b) (4)	17 Sep 2020 00:28:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:05
	(b) (4), (b) (6)	
User opened query 'Please verify, per source document value is 98.9. ' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 19:32:54
User entered '98.8' F	Kelly Woodell (b) (4)	16 Aug 2020 13:33:13
	(b) (4)	

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:14
User entered 'Oral (Oral)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:16
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:21
User entered '81'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:23
User entered '12'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:28
User entered '123'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:33:30
User entered '77'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Aug 2020 13:33:13

US3822015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:19
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:33

US3822015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:19
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:33

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Aug 2020 17:11:43
	(b) (4)	

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered empty.	Kelly Woodell (b) (4)	05 Aug 2020 17:11:43
	(b) (4)	

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered '13:05'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:05'	System	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4) (b) (4)	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:34:53
User entered 'ONCE'	System	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 17:11:43

US3822015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:22
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:55

US3822015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:22
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:55

US3822015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:22
User entered '12:46'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:33:55

US3822015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:46'	System	16 Aug 2020 13:33:55

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:22:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:33
User entered '05 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:33
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	16 Aug 2020 13:34:11
	(b) (4)	

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:33
User entered '12:57'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:57'	System	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:33
User entered 'No (N)'	Kelly Woodell (b) (4)	16 Aug 2020 13:34:11
	(b) (4)	

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:33
User entered empty.	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 13:34:11

US3822015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:35:43
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	16 Aug 2020 13:34:16

US3822015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 13:34:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:34:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a24e9387-2618-4460-8ef0-947e051ce65a'	System	05 Aug 2020 17:35:26
User entered 'Yes (Y)'	System	05 Aug 2020 17:35:26

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:34:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a24e9387-2618-4460-8ef0-947e051ce65a'	System	05 Aug 2020 17:35:26
User entered '98.8'	System	05 Aug 2020 17:35:26

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:34:59', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a24e9387-2618-4460-8ef0-947e051ce65a'	System	05 Aug 2020 17:35:26
User entered 'Yes (Y)'	System	05 Aug 2020 17:35:26

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:35:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a24e9387-2618-4460-8ef0-947e051ce65a'	System	05 Aug 2020 17:35:26
User entered '0'	System	05 Aug 2020 17:35:26

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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 'Per day 8 phone call the patient denied taking any new medications for pain or fever' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 17:09:29
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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:35:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a24e9387-2618-4460-8ef0-947e051ce65a' User entered '1'	Kelly Woodell (b) (4)	26 Aug 2020 01:37:44
	System	05 Aug 2020 17:35:26
	System	05 Aug 2020 17:35:26
	System	05 Aug 2020 17:35:26

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:35:24', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a24e9387-2618-4460-8ef0-947e051ce65a'	System	05 Aug 2020 17:35:26
User entered '05 Aug 2020 13:35'	System	05 Aug 2020 17:35:26

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:25'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 15:55'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:19:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '662c7a71-e50f-48bd-8d08-f521d8d11fce'	System	06 Aug 2020 11:20:12
User entered 'Yes (Y)'	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:19:46', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '662c7a71-e50f-48bd-8d08-f521d8d11fce'	System	06 Aug 2020 11:20:12
User entered '97.1'	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:19:52', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '662c7a71-e50f-48bd-8d08-f521d8d11fce'	System	06 Aug 2020 11:20:12
User entered 'No (N)'	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:20:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '662c7a71-e50f-48bd-8d08-f521d8d11fce'	System	06 Aug 2020 11:20:12
User entered '06 Aug 2020 07:20'	System	06 Aug 2020 11:20:12

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 16:50'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 2'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:32:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '55c7f0a8-ec99-4a78-8d0b-43bb4508f0bf'	System	07 Aug 2020 10:32:52
User entered 'Yes (Y)'	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:32:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '55c7f0a8-ec99-4a78-8d0b-43bb4508f0bf'	System	07 Aug 2020 10:32:52
User entered '97.2'	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:32:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '55c7f0a8-ec99-4a78-8d0b-43bb4508f0bf'	System	07 Aug 2020 10:32:52
User entered 'No (N)'	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:32:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '55c7f0a8-ec99-4a78-8d0b-43bb4508f0bf'	System	07 Aug 2020 10:32:52
User entered '07 Aug 2020 06:32'	System	07 Aug 2020 10:32:52

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 3'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:52:53', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e125c91d-a857-45a8-bff7-34071511ad30'	System	07 Aug 2020 16:53:25
User entered 'Yes (Y)'	System	07 Aug 2020 16:53:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:53:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e125c91d-a857-45a8-bff7-34071511ad30'	System	07 Aug 2020 16:53:25
User entered '97.1'	System	07 Aug 2020 16:53:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:53:14', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e125c91d-a857-45a8-bff7-34071511ad30'	System	07 Aug 2020 16:53:25
User entered 'No (N)'	System	07 Aug 2020 16:53:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:53:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e125c91d-a857-45a8-bff7-34071511ad30'	System	07 Aug 2020 16:53:25
User entered '07 Aug 2020 12:53'	System	07 Aug 2020 16:53:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 4'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:55:03', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '0e49c168-2afd-40b5-988b-b1cf96aa3166'	System	09 Aug 2020 01:55:38
User entered 'Yes (Y)'	System	09 Aug 2020 01:55:38

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:55:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '0e49c168-2afd-40b5-988b-b1cf96aa3166'	System	09 Aug 2020 01:55:38
User entered '97.6'	System	09 Aug 2020 01:55:38

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:55:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '0e49c168-2afd-40b5-988b-b1cf96aa3166'	System	09 Aug 2020 01:55:38
User entered 'No (N)'	System	09 Aug 2020 01:55:38

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:55:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '0e49c168-2afd-40b5-988b-b1cf96aa3166'	System	09 Aug 2020 01:55:38
User entered '08 Aug 2020 21:55'	System	09 Aug 2020 01:55:38

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 5'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:10:03', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'bfc357fe-0221-47db-9d68-d61c46a83c2e'	System	10 Aug 2020 02:10:25
User entered 'Yes (Y)'	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:10:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'bfc357fe-0221-47db-9d68-d61c46a83c2e'	System	10 Aug 2020 02:10:25
User entered '97.5'	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:10:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'bfc357fe-0221-47db-9d68-d61c46a83c2e'	System	10 Aug 2020 02:10:25
User entered 'No (N)'	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:10:23', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'bfc357fe-0221-47db-9d68-d61c46a83c2e'	System	10 Aug 2020 02:10:25
User entered '09 Aug 2020 22:10'	System	10 Aug 2020 02:10:25

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 6'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:09:24', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd12bbc77-70e6-4af2-940b-f8bb0cdd5235'	System	11 Aug 2020 02:10:16
User entered 'Yes (Y)'	System	11 Aug 2020 02:10:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:09:38', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd12bbc77-70e6-4af2-940b-f8bb0cdd5235'	System	11 Aug 2020 02:10:16
User entered '96.8'	System	11 Aug 2020 02:10:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:09:58', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd12bbc77-70e6-4af2-940b-f8bb0cdd5235'	System	11 Aug 2020 02:10:16
User entered 'No (N)'	System	11 Aug 2020 02:10:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:10:14', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd12bbc77-70e6-4af2-940b-f8bb0cdd5235'	System	11 Aug 2020 02:10:16
User entered '10 Aug 2020 22:10'	System	11 Aug 2020 02:10:16

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 7'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:04:01', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a66ac17d-2f88-4138-b606-45ca05cb629a'	System	12 Aug 2020 02:04:33
User entered 'Yes (Y)'	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:04:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a66ac17d-2f88-4138-b606-45ca05cb629a'	System	12 Aug 2020 02:04:33
User entered '97.0'	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:04:18', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a66ac17d-2f88-4138-b606-45ca05cb629a'	System	12 Aug 2020 02:04:33
User entered 'No (N)'	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:04:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a66ac17d-2f88-4138-b606-45ca05cb629a'	System	12 Aug 2020 02:04:33
User entered '11 Aug 2020 22:04'	System	12 Aug 2020 02:04:33

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:31:55', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '48470ae4-25d6-4e99-b7fa-0a52daa769d7'	System	05 Aug 2020 17:33:01
User entered 'None (1)'	System	05 Aug 2020 17:33:01

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:32:01', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '48470ae4-25d6-4e99-b7fa-0a52daa769d7'	System	05 Aug 2020 17:33:01
User entered 'No (N)'	System	05 Aug 2020 17:33:01

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:32:07', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '48470ae4-25d6-4e99-b7fa-0a52daa769d7'	System	05 Aug 2020 17:33:01
User entered 'No (N)'	System	05 Aug 2020 17:33:01

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:32:28', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '48470ae4-25d6-4e99-b7fa-0a52daa769d7'	System	05 Aug 2020 17:33:01
User entered 'None (1)'	System	05 Aug 2020 17:33:01

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:32:58', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '48470ae4-25d6-4e99-b7fa-0a52daa769d7'	System	05 Aug 2020 17:33:01
User entered '05 Aug 2020 13:32'	System	05 Aug 2020 17:33:01

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:25'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 15:55'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:20:25', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '411831ed-4f1a-4fbb-8590-4fece6c34b3b'	System	06 Aug 2020 11:21:50
User entered 'None (1)'	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:21:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '411831ed-4f1a-4fbb-8590-4fece6c34b3b'	System	06 Aug 2020 11:21:50
User entered 'No (N)'	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:21:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '411831ed-4f1a-4fbb-8590-4fece6c34b3b'	System	06 Aug 2020 11:21:50
User entered 'No (N)'	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:21:32', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '411831ed-4f1a-4fbb-8590-4fece6c34b3b'	System	06 Aug 2020 11:21:50
User entered 'None (1)'	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:21:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '411831ed-4f1a-4fbb-8590-4fece6c34b3b'	System	06 Aug 2020 11:21:50
User entered '06 Aug 2020 07:21'	System	06 Aug 2020 11:21:50

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 16:50'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 2'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:02', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f361ebf3-fd03-4b19-96b1-ace709522a1f'	System	07 Aug 2020 10:33:38
User entered 'None (1)'	System	07 Aug 2020 10:33:38

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:06', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f361ebf3-fd03-4b19-96b1-ace709522a1f'	System	07 Aug 2020 10:33:38
User entered 'No (N)'	System	07 Aug 2020 10:33:38

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f361ebf3-fd03-4b19-96b1-ace709522a1f'	System	07 Aug 2020 10:33:38
User entered 'No (N)'	System	07 Aug 2020 10:33:38

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:26', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f361ebf3-fd03-4b19-96b1-ace709522a1f'	System	07 Aug 2020 10:33:38
User entered 'None (1)'	System	07 Aug 2020 10:33:38

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:37', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f361ebf3-fd03-4b19-96b1-ace709522a1f' User entered '07 Aug 2020 06:33'	System	07 Aug 2020 10:33:38
	System	07 Aug 2020 10:33:38

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 3'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:53:37', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a6f899ef-e48b-43fc-a4a0-e44e9e0e5155'	System	07 Aug 2020 16:54:29
User entered 'None (1)'	System	07 Aug 2020 16:54:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:53:44', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a6f899ef-e48b-43fc-a4a0-e44e9e0e5155'	System	07 Aug 2020 16:54:29
User entered 'No (N)'	System	07 Aug 2020 16:54:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:53:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a6f899ef-e48b-43fc-a4a0-e44e9e0e5155'	System	07 Aug 2020 16:54:29
User entered 'No (N)'	System	07 Aug 2020 16:54:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a6f899ef-e48b-43fc-a4a0-e44e9e0e5155'	System	07 Aug 2020 16:54:29
User entered 'None (1)'	System	07 Aug 2020 16:54:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:25', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a6f899ef-e48b-43fc-a4a0-e44e9e0e5155'	System	07 Aug 2020 16:54:29
User entered '07 Aug 2020 12:54'	System	07 Aug 2020 16:54:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 4'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:56:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '31fc1a1e-2594-4cdf-946d-08146088cc8b'	System	09 Aug 2020 01:57:00
User entered 'None (1)'	System	09 Aug 2020 01:57:00

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:56:25', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '31fc1a1e-2594-4cdf-946d-08146088cc8b'	System	09 Aug 2020 01:57:00
User entered 'No (N)'	System	09 Aug 2020 01:57:00

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:56:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '31fc1a1e-2594-4cdf-946d-08146088cc8b'	System	09 Aug 2020 01:57:00
User entered 'No (N)'	System	09 Aug 2020 01:57:00

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:56:45', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '31fc1a1e-2594-4cdf-946d-08146088cc8b' User entered 'None (1)'	System	09 Aug 2020 01:57:00
	System	09 Aug 2020 01:57:00

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:56:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '31fc1a1e-2594-4cdf-946d-08146088cc8b'	System	09 Aug 2020 01:57:00
User entered '08 Aug 2020 21:56'	System	09 Aug 2020 01:57:00

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 5'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c5d462cb-1efc-487f-8a55-8802951b505f'	System	10 Aug 2020 02:11:29
User entered 'None (1)'	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:10:48', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c5d462cb-1efc-487f-8a55-8802951b505f'	System	10 Aug 2020 02:11:29
User entered 'No (N)'	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:10:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c5d462cb-1efc-487f-8a55-8802951b505f'	System	10 Aug 2020 02:11:29
User entered 'No (N)'	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:03', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c5d462cb-1efc-487f-8a55-8802951b505f'	System	10 Aug 2020 02:11:29
User entered 'None (1)'	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:28', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'c5d462cb-1efc-487f-8a55-8802951b505f'	System	10 Aug 2020 02:11:29
User entered '09 Aug 2020 22:11'	System	10 Aug 2020 02:11:29

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 6'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:10:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '660503f4-4928-465a-b542-c069b1ca382e'	System	11 Aug 2020 02:11:19
User entered 'None (1)'	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:10:33', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '660503f4-4928-465a-b542-c069b1ca382e'	System	11 Aug 2020 02:11:19
User entered 'No (N)'	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:10:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '660503f4-4928-465a-b542-c069b1ca382e'	System	11 Aug 2020 02:11:19
User entered 'No (N)'	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:10:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '660503f4-4928-465a-b542-c069b1ca382e'	System	11 Aug 2020 02:11:19
User entered 'None (1)'	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:16', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '660503f4-4928-465a-b542-c069b1ca382e'	System	11 Aug 2020 02:11:19
User entered '10 Aug 2020 22:11'	System	11 Aug 2020 02:11:19

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 7'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:05:40', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7270e72-d7c6-440b-bd7f-bf79b85dd0a8'	System	12 Aug 2020 02:06:17
User entered 'None (1)'	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:05:44', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7270e72-d7c6-440b-bd7f-bf79b85dd0a8'	System	12 Aug 2020 02:06:17
User entered 'No (N)'	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:05:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7270e72-d7c6-440b-bd7f-bf79b85dd0a8'	System	12 Aug 2020 02:06:17
User entered 'No (N)'	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:05:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7270e72-d7c6-440b-bd7f-bf79b85dd0a8'	System	12 Aug 2020 02:06:17
User entered 'None (1)'	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:15', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7270e72-d7c6-440b-bd7f-bf79b85dd0a8'	System	12 Aug 2020 02:06:17
User entered '11 Aug 2020 22:06'	System	12 Aug 2020 02:06:17

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:35:48', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered 'None (0)'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:35:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered 'None (0)'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:36:03', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered 'None (0)'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:37:04', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered 'None (0)'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:37:08', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered 'None (0)'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:37:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered 'None (0)'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:38:19', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered 'No (N)'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-05T13:38:40', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '82cb8868-6651-4e5b-a2c8-35538f6197c6'	System	05 Aug 2020 17:38:45
User entered '05 Aug 2020 13:38'	System	05 Aug 2020 17:38:45

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:25'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 15:55'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:21:58', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered 'None (0)'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:22:03', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered 'None (0)'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:22:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered 'None (0)'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:22:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered 'None (0)'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:22:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered 'None (0)'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:22:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered 'None (0)'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:22:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered 'No (N)'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-06T07:22:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e98e0b4d-48f5-4f28-bf3e-58f5607b7fbc'	System	06 Aug 2020 11:22:42
User entered '06 Aug 2020 07:22'	System	06 Aug 2020 11:22:42

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 16:50'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 2'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:45', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered 'None (0)'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered 'None (0)'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:33:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered 'None (0)'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:34:01', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered 'None (0)'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:34:05', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered 'None (0)'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:34:08', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered 'None (0)'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:34:16', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered 'No (N)'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T06:34:27', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'e8ca73ff-63bd-439d-b95a-044be0352033'	System	07 Aug 2020 10:34:29
User entered '07 Aug 2020 06:34'	System	07 Aug 2020 10:34:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 3'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:32', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e'	System	07 Aug 2020 16:55:29
User entered 'None (0)'	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e' User entered 'None (0)'	System	07 Aug 2020 16:55:29
	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:40', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e' User entered 'None (0)'	System	07 Aug 2020 16:55:29
	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:48', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e' User entered 'None (0)'	System	07 Aug 2020 16:55:29
	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:52', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e' User entered 'None (0)'	System	07 Aug 2020 16:55:29
	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:54:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e'	System	07 Aug 2020 16:55:29
User entered 'None (0)'	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:55:10', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e'	System	07 Aug 2020 16:55:29
User entered 'No (N)'	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-07T12:55:27', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8e9b53b8-fd01-45da-a944-e66db8d5db6e'	System	07 Aug 2020 16:55:29
User entered '07 Aug 2020 12:55'	System	07 Aug 2020 16:55:29

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 4'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f'	System	09 Aug 2020 01:58:01
User entered 'None (0)'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f'	System	09 Aug 2020 01:58:01
User entered 'None (0)'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f'	System	09 Aug 2020 01:58:01
User entered 'None (0)'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f'	System	09 Aug 2020 01:58:01
User entered 'None (0)'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:26', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f'	System	09 Aug 2020 01:58:01
User entered 'None (0)'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f'	System	09 Aug 2020 01:58:01
User entered 'None (0)'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:37', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f'	System	09 Aug 2020 01:58:01
User entered 'No (N)'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-08T21:57:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea83d7f9-0325-4106-9c9c-0c13c3d4ae9f' User entered '08 Aug 2020 21:57'	System	09 Aug 2020 01:58:01

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 5'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:40', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered 'None (0)'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:45', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered 'None (0)'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered 'None (0)'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:55', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered 'None (0)'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:11:59', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered 'None (0)'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:12:04', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered 'None (0)'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:12:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered 'No (N)'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-09T22:12:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ab0510d8-654c-48ce-a750-cc2baa0103ab'	System	10 Aug 2020 02:12:31
User entered '09 Aug 2020 22:12'	System	10 Aug 2020 02:12:31

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 6'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:25', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered 'None (0)'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered 'None (0)'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered 'None (0)'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:40', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered 'None (0)'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:46', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered 'None (0)'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered 'None (0)'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:11:59', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered 'No (N)'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-10T22:12:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '8c74d9de-9f71-4dc4-a8c8-0e2454af4dbb'	System	11 Aug 2020 02:12:15
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 02:12:15

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 7'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:23', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered 'None (0)'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:27', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered 'None (0)'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:32', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered 'None (0)'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered 'None (0)'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered 'None (0)'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:42', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered 'None (0)'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:06:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered 'No (N)'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-08-11T22:07:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b9ea6b8c-0f82-4fd1-9d0c-af576f3fe69c'	System	12 Aug 2020 02:07:13
User entered '11 Aug 2020 22:07'	System	12 Aug 2020 02:07:13

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 17:11:43

US3822015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:21
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:39:51

US3822015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:21
User entered '13 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:39:51

US3822015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:21
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:39:51

US3822015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:21
User entered empty.	Kelly Woodell (b) (4)	25 Aug 2020 22:39:51

US3822015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:25:55
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	25 Aug 2020 22:39:54

US3822015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 22:39:54

US3822015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:39:06
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:40:04

US3822015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:39:06
User entered '21 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:40:04

US3822015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:39:06
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:40:04

US3822015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:39:06
User entered empty.	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:40:04

US3822015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:55
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	25 Aug 2020 22:40:07

US3822015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 22:40:07

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	03 Sep 2020 15:59:09

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered '27 Aug 2020'	Kelly Woodell (b) (4)	03 Sep 2020 15:59:09
	(b) (4)	

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	03 Sep 2020 15:59:09

US3822015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 16:01:13
User entered empty.	Kelly Woodell (b) (4)	03 Sep 2020 15:59:09

US3822015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 16:01:20
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:57:33

US3822015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 15:57:33

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:35:42
User closed query 'Please complete all Visit 2 EDC pages.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 13:32:23
Query 'Please complete all Visit 2 EDC pages.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4)	28 Sep 2020 21:32:33
User opened query 'Please complete all Visit 2 EDC pages.' (Site from CRA).	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 19:14:09
	Kelly Woodell (b) (4)	03 Sep 2020 15:57:50
	(b) (4)	

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:35:42
User entered '03 Sep 2020'	Kelly Woodell (b) (4)	03 Sep 2020 15:57:50

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:35:42
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	03 Sep 2020 15:57:50

US3822015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	03 Sep 2020 15:57:50

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '3 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '11:00'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered '3 Sep 2020 11:00'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '97.8' F	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered 'Oral (Oral)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '68'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '16'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '120'	Krishna Shah (b) (4)	28 Sep 2020 21:27:12
	(b) (4)	

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '82'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 21:27:12

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '3 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '12:17'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered '3 Sep 2020 12:17'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '98.4' F	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered 'Oral (Oral)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '78'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '14'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '121'	Krishna Shah (b) (4)	28 Sep 2020 21:27:42
	(b) (4)	

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:36:12
User entered '81'	Krishna Shah (b) (4)	28 Sep 2020 21:27:42
	(b) (4)	

US3822015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 21:27:42

US3822015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:17
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:52

US3822015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:17
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:27:52

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered empty.	Kelly Woodell (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered empty.	Kelly Woodell (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered '03 Sep 2020'	Kelly Woodell (b) (4)	03 Sep 2020 15:58:09
	(b) (4)	

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered '11:47'	Kelly Woodell (b) (4) (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:47'	System	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered 'Left Arm (LEFT ARM)'	Kelly Woodell (b) (4)	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:37:53
User entered 'ONCE'	System	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:22:22

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 15:58:09

US3822015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:20
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:06

US3822015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:20
User entered '3 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:06

US3822015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:20
User entered '11:11'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:06

US3822015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 11:11'	System	28 Sep 2020 21:28:06

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:22:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:29
User entered '3 Sep 2020'	Krishna Shah (b) (4)	28 Sep 2020 21:28:22
	(b) (4)	

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:35
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:35
User entered '11:26'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:22:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 11:26'	System	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Krishna Shah (b) (4)	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:35
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:35
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:22:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:28:22

US3822015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:38:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:28:26

US3822015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:28:26

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:10:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b7f6593b-58fe-49a5-9653-fed08b1a67d4'	System	03 Sep 2020 16:10:52
User entered 'Yes (Y)'	System	03 Sep 2020 16:10:52

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:10:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b7f6593b-58fe-49a5-9653-fed08b1a67d4'	System	03 Sep 2020 16:10:52
User entered '98.4'	System	03 Sep 2020 16:10:52

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:10:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b7f6593b-58fe-49a5-9653-fed08b1a67d4'	System	03 Sep 2020 16:10:52
User entered 'No (N)'	System	03 Sep 2020 16:10:52

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:10:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b7f6593b-58fe-49a5-9653-fed08b1a67d4'	System	03 Sep 2020 16:10:52
User entered '03 Sep 2020 12:10'	System	03 Sep 2020 16:10:52

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:07'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:37'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:33:02', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '027400a5-3520-48b6-adbd-98d4294a815c'	System	04 Sep 2020 01:33:33
User entered 'Yes (Y)'	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:33:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '027400a5-3520-48b6-adbd-98d4294a815c'	System	04 Sep 2020 01:33:33
User entered '97.9'	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:33:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '027400a5-3520-48b6-adbd-98d4294a815c'	System	04 Sep 2020 01:33:33
User entered 'No (N)'	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:33:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '027400a5-3520-48b6-adbd-98d4294a815c'	System	04 Sep 2020 01:33:33
User entered '03 Sep 2020 21:33'	System	04 Sep 2020 01:33:33

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 15:32'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 2'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:47:52', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '2ae60e7a-3b8d-44db-8c3c-8a04bce67e8c'	System	05 Sep 2020 01:48:19
User entered 'Yes (Y)'	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:47:59', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '2ae60e7a-3b8d-44db-8c3c-8a04bce67e8c'	System	05 Sep 2020 01:48:19
User entered '97.3'	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:48:07', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '2ae60e7a-3b8d-44db-8c3c-8a04bce67e8c'	System	05 Sep 2020 01:48:19
User entered 'No (N)'	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:48:14', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '2ae60e7a-3b8d-44db-8c3c-8a04bce67e8c'	System	05 Sep 2020 01:48:19
User entered '04 Sep 2020 21:48'	System	05 Sep 2020 01:48:19

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 3'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:15:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aa0ba949-ca5e-4589-af4f-2ddf4b77e581'	System	06 Sep 2020 02:15:45
User entered 'Yes (Y)'	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:15:27', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aa0ba949-ca5e-4589-af4f-2ddf4b77e581'	System	06 Sep 2020 02:15:45
User entered '97.4'	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:15:34', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aa0ba949-ca5e-4589-af4f-2ddf4b77e581'	System	06 Sep 2020 02:15:45
User entered 'No (N)'	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:15:43', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aa0ba949-ca5e-4589-af4f-2ddf4b77e581'	System	06 Sep 2020 02:15:45
User entered '05 Sep 2020 22:15'	System	06 Sep 2020 02:15:45

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 4'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:55:45', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aee76bab-7705-4275-a010-48d6b3b9b787'	System	07 Sep 2020 01:56:12
User entered 'Yes (Y)'	System	07 Sep 2020 01:56:12

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:55:55', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aee76bab-7705-4275-a010-48d6b3b9b787'	System	07 Sep 2020 01:56:12
User entered '97.4'	System	07 Sep 2020 01:56:12

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:56:02', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aee76bab-7705-4275-a010-48d6b3b9b787'	System	07 Sep 2020 01:56:12
User entered 'No (N)'	System	07 Sep 2020 01:56:12

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:56:08', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'aee76bab-7705-4275-a010-48d6b3b9b787'	System	07 Sep 2020 01:56:12
User entered '06 Sep 2020 21:56'	System	07 Sep 2020 01:56:12

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 5'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:07:46', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '74ca69a4-348e-4cb1-a9db-7fac45c5ffdc'	System	08 Sep 2020 02:08:17
User entered 'Yes (Y)'	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:07:55', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '74ca69a4-348e-4cb1-a9db-7fac45c5ffdc'	System	08 Sep 2020 02:08:17
User entered '97.8'	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:08:05', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '74ca69a4-348e-4cb1-a9db-7fac45c5ffdc'	System	08 Sep 2020 02:08:17
User entered 'No (N)'	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:08:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '74ca69a4-348e-4cb1-a9db-7fac45c5ffdc'	System	08 Sep 2020 02:08:17
User entered '07 Sep 2020 22:08'	System	08 Sep 2020 02:08:17

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 6'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:58:09', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7e8e6d9f-4992-4bf0-97c9-57b99c34cdc3'	System	09 Sep 2020 00:58:36
User entered 'Yes (Y)'	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:58:16', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7e8e6d9f-4992-4bf0-97c9-57b99c34cdc3'	System	09 Sep 2020 00:58:36
User entered '97.4'	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:58:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7e8e6d9f-4992-4bf0-97c9-57b99c34cdc3'	System	09 Sep 2020 00:58:36
User entered 'No (N)'	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:58:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '7e8e6d9f-4992-4bf0-97c9-57b99c34cdc3'	System	09 Sep 2020 00:58:36
User entered '08 Sep 2020 20:58'	System	09 Sep 2020 00:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 7'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:20:33', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd84c7cef-eb6f-43bb-883b-c550bfb689fd'	System	10 Sep 2020 00:21:04
User entered 'Yes (Y)'	System	10 Sep 2020 00:21:04

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:20:42', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd84c7cef-eb6f-43bb-883b-c550bfb689fd'	System	10 Sep 2020 00:21:04
User entered '98.2'	System	10 Sep 2020 00:21:04

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:20:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd84c7cef-eb6f-43bb-883b-c550bfb689fd'	System	10 Sep 2020 00:21:04
User entered 'No (N)'	System	10 Sep 2020 00:21:04

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:21:01', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd84c7cef-eb6f-43bb-883b-c550bfb689fd'	System	10 Sep 2020 00:21:04
User entered '09 Sep 2020 20:21'	System	10 Sep 2020 00:21:04

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:01', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d17fa81-91e6-4864-94d6-198f9613f396'	System	03 Sep 2020 16:11:42
User entered 'None (1)'	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:14', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d17fa81-91e6-4864-94d6-198f9613f396'	System	03 Sep 2020 16:11:42
User entered 'No (N)'	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:23', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d17fa81-91e6-4864-94d6-198f9613f396'	System	03 Sep 2020 16:11:42
User entered 'No (N)'	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d17fa81-91e6-4864-94d6-198f9613f396'	System	03 Sep 2020 16:11:42
User entered 'None (1)'	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '6d17fa81-91e6-4864-94d6-198f9613f396'	System	03 Sep 2020 16:11:42
User entered '03 Sep 2020 12:11'	System	03 Sep 2020 16:11:42

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:07'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:37'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:33:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea13ca25-927b-4fa7-925e-47810fcaa946'	System	04 Sep 2020 01:34:54
User entered 'None (1)'	System	04 Sep 2020 01:34:54

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:34:15', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea13ca25-927b-4fa7-925e-47810fcaa946'	System	04 Sep 2020 01:34:54
User entered 'No (N)'	System	04 Sep 2020 01:34:54

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:34:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea13ca25-927b-4fa7-925e-47810fcaa946'	System	04 Sep 2020 01:34:54
User entered 'No (N)'	System	04 Sep 2020 01:34:54

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:34:34', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea13ca25-927b-4fa7-925e-47810fcaa946'	System	04 Sep 2020 01:34:54
User entered 'None (1)'	System	04 Sep 2020 01:34:54

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:34:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ea13ca25-927b-4fa7-925e-47810fcaa946'	System	04 Sep 2020 01:34:54
User entered '03 Sep 2020 21:34'	System	04 Sep 2020 01:34:54

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 15:32'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 2'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:49:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40ab87b5-4cfa-4ae8-9acf-3c1bc821e204'	System	05 Sep 2020 01:49:48
User entered 'None (1)'	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:49:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40ab87b5-4cfa-4ae8-9acf-3c1bc821e204'	System	05 Sep 2020 01:49:48
User entered 'No (N)'	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:49:24', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40ab87b5-4cfa-4ae8-9acf-3c1bc821e204'	System	05 Sep 2020 01:49:48
User entered 'No (N)'	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:49:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40ab87b5-4cfa-4ae8-9acf-3c1bc821e204'	System	05 Sep 2020 01:49:48
User entered 'None (1)'	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:49:43', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40ab87b5-4cfa-4ae8-9acf-3c1bc821e204'	System	05 Sep 2020 01:49:48
User entered '04 Sep 2020 21:49'	System	05 Sep 2020 01:49:48

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 3'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:15:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'acba934d-49e9-4188-8511-ece94b1d688e' User entered 'None (1)'	System	06 Sep 2020 02:16:25
	System	06 Sep 2020 02:16:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:15:55', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'acba934d-49e9-4188-8511-ece94b1d688e' User entered 'No (N)'	System	06 Sep 2020 02:16:25
	System	06 Sep 2020 02:16:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:01', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'acba934d-49e9-4188-8511-ece94b1d688e'	System	06 Sep 2020 02:16:25
User entered 'No (N)'	System	06 Sep 2020 02:16:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:13', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'acba934d-49e9-4188-8511-ece94b1d688e'	System	06 Sep 2020 02:16:25
User entered 'None (1)'	System	06 Sep 2020 02:16:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:24', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'acba934d-49e9-4188-8511-ece94b1d688e'	System	06 Sep 2020 02:16:25
User entered '05 Sep 2020 22:16'	System	06 Sep 2020 02:16:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 4'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:56:46', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '67c089d8-32a8-4003-bc11-698427d5ba9e'	System	07 Sep 2020 01:57:23
User entered 'None (1)'	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:56:53', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '67c089d8-32a8-4003-bc11-698427d5ba9e'	System	07 Sep 2020 01:57:23
User entered 'No (N)'	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:00', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '67c089d8-32a8-4003-bc11-698427d5ba9e'	System	07 Sep 2020 01:57:23
User entered 'No (N)'	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:08', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '67c089d8-32a8-4003-bc11-698427d5ba9e'	System	07 Sep 2020 01:57:23
User entered 'None (1)'	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '67c089d8-32a8-4003-bc11-698427d5ba9e'	System	07 Sep 2020 01:57:23
User entered '06 Sep 2020 21:57'	System	07 Sep 2020 01:57:23

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 5'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:08:41', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b61368de-2f08-4222-ae2c-c913dc009600'	System	08 Sep 2020 02:09:19
User entered 'None (1)'	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:08:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b61368de-2f08-4222-ae2c-c913dc009600'	System	08 Sep 2020 02:09:19
User entered 'No (N)'	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:08:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b61368de-2f08-4222-ae2c-c913dc009600'	System	08 Sep 2020 02:09:19
User entered 'No (N)'	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:05', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b61368de-2f08-4222-ae2c-c913dc009600'	System	08 Sep 2020 02:09:19
User entered 'None (1)'	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:15', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'b61368de-2f08-4222-ae2c-c913dc009600'	System	08 Sep 2020 02:09:19
User entered '07 Sep 2020 22:09'	System	08 Sep 2020 02:09:19

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 6'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:58:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ce19abab-09ee-4e84-9e2c-531324c47447'	System	09 Sep 2020 00:59:25
User entered 'None (1)'	System	09 Sep 2020 00:59:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:02', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ce19abab-09ee-4e84-9e2c-531324c47447'	System	09 Sep 2020 00:59:25
User entered 'No (N)'	System	09 Sep 2020 00:59:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:05', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ce19abab-09ee-4e84-9e2c-531324c47447'	System	09 Sep 2020 00:59:25
User entered 'No (N)'	System	09 Sep 2020 00:59:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:14', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ce19abab-09ee-4e84-9e2c-531324c47447'	System	09 Sep 2020 00:59:25
User entered 'None (1)'	System	09 Sep 2020 00:59:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:23', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ce19abab-09ee-4e84-9e2c-531324c47447'	System	09 Sep 2020 00:59:25
User entered '08 Sep 2020 20:59'	System	09 Sep 2020 00:59:25

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 7'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:21:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7ba1d6b-74e7-4440-b613-6945e695556b'	System	10 Sep 2020 00:22:05
User entered 'None (1)'	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:21:26', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7ba1d6b-74e7-4440-b613-6945e695556b'	System	10 Sep 2020 00:22:05
User entered 'No (N)'	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:21:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7ba1d6b-74e7-4440-b613-6945e695556b'	System	10 Sep 2020 00:22:05
User entered 'No (N)'	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:21:43', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7ba1d6b-74e7-4440-b613-6945e695556b'	System	10 Sep 2020 00:22:05
User entered 'None (1)'	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:01', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f7ba1d6b-74e7-4440-b613-6945e695556b'	System	10 Sep 2020 00:22:05
User entered '09 Sep 2020 20:22'	System	10 Sep 2020 00:22:05

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:47', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered 'None (0)'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered 'None (0)'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:11:59', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered 'None (0)'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:12:04', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered 'None (0)'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:12:07', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered 'None (0)'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:12:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered 'None (0)'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:12:18', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered 'No (N)'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T12:12:32', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '85b83251-0a5e-473f-9f0d-55089ae04dc5'	System	03 Sep 2020 16:12:35
User entered '03 Sep 2020 12:12'	System	03 Sep 2020 16:12:35

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:07'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:37'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:34:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521'	System	04 Sep 2020 01:35:57
User entered 'None (0)'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:35:03', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521'	System	04 Sep 2020 01:35:57
User entered 'None (0)'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:35:12', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521' User entered 'None (0)'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:35:18', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521'	System	04 Sep 2020 01:35:57
User entered 'None (0)'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:35:23', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521'	System	04 Sep 2020 01:35:57
User entered 'None (0)'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:35:26', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521'	System	04 Sep 2020 01:35:57
User entered 'None (0)'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:35:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521'	System	04 Sep 2020 01:35:57
User entered 'No (N)'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-03T21:35:52', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'a8efeb92-f2dd-46e6-bd29-f10fb23e2521'	System	04 Sep 2020 01:35:57
User entered '03 Sep 2020 21:35'	System	04 Sep 2020 01:35:57

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 15:32'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 2'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:49:53', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b'	System	05 Sep 2020 01:51:23
User entered 'None (0)'	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:50:07', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b' User entered 'None (0)'	System	05 Sep 2020 01:51:23
	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:50:14', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b'	System	05 Sep 2020 01:51:23
User entered 'None (0)'	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:50:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b'	System	05 Sep 2020 01:51:23
User entered 'None (0)'	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:50:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b' User entered 'None (0)'	System	05 Sep 2020 01:51:23
	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:50:34', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b' User entered 'None (0)'	System	05 Sep 2020 01:51:23
	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:50:58', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b'	System	05 Sep 2020 01:51:23
User entered 'No (N)'	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-04T21:51:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'cbf7232e-b59d-45c7-a063-b796220a761b'	System	05 Sep 2020 01:51:23
User entered '04 Sep 2020 21:51'	System	05 Sep 2020 01:51:23

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 3'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:34', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered 'None (0)'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered 'None (0)'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:45', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered 'None (0)'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered 'None (0)'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:16:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered 'None (0)'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:17:03', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered 'None (0)'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:17:26', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered 'No (N)'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-05T22:17:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'ad0cc454-7dc9-406c-83eb-062326812316'	System	06 Sep 2020 02:17:40
User entered '05 Sep 2020 22:17'	System	06 Sep 2020 02:17:40

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 4'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered 'None (0)'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:37', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered 'None (0)'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:43', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered 'None (0)'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:47', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered 'None (0)'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:57:58', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered 'None (0)'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:58:05', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered 'None (0)'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:58:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered 'No (N)'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-06T21:58:33', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '40cf8f69-f7c5-4969-bf04-93694fcb293a'	System	07 Sep 2020 01:58:36
User entered '06 Sep 2020 21:58'	System	07 Sep 2020 01:58:36

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 5'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:21', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e' User entered 'None (0)'	System	08 Sep 2020 02:10:16
	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:25', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e' User entered 'None (0)'	System	08 Sep 2020 02:10:16
	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e' User entered 'None (0)'	System	08 Sep 2020 02:10:16
	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:35', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e' User entered 'None (0)'	System	08 Sep 2020 02:10:16
	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:41', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e' User entered 'None (0)'	System	08 Sep 2020 02:10:16
	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:44', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e' User entered 'None (0)'	System	08 Sep 2020 02:10:16
	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:09:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e'	System	08 Sep 2020 02:10:16
User entered 'No (N)'	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-07T22:10:14', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9302377a-c9b5-4997-9ae0-e1c7cbc6492e'	System	08 Sep 2020 02:10:16
User entered '07 Sep 2020 22:10'	System	08 Sep 2020 02:10:16

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 6'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:30', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8'	System	09 Sep 2020 01:00:18
User entered 'None (0)'	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:34', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8'	System	09 Sep 2020 01:00:18
User entered 'None (0)'	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:37', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8'	System	09 Sep 2020 01:00:18
User entered 'None (0)'	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:42', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8'	System	09 Sep 2020 01:00:18
User entered 'None (0)'	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:45', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8'	System	09 Sep 2020 01:00:18
User entered 'None (0)'	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:49', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8' User entered 'None (0)'	System	09 Sep 2020 01:00:18
	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T20:59:58', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8'	System	09 Sep 2020 01:00:18
User entered 'No (N)'	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-08T21:00:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '65404d4c-6c9c-4fc2-a75b-489b4118fbb8'	System	09 Sep 2020 01:00:18
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 01:00:18

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:58:09
User entered 'Day 7'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:10', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered 'None (0)'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:15', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered 'None (0)'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:20', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered 'None (0)'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:26', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered 'None (0)'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:31', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered 'None (0)'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:39', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered 'None (0)'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:47', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered 'No (N)'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-09-09T20:22:57', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'dcca9d24-6df1-4631-85bd-d573fd756ec2'	System	10 Sep 2020 00:23:01
User entered '09 Sep 2020 20:22'	System	10 Sep 2020 00:23:01

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:58:09

US3822015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:58:09

US3822015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:48:22
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:32:59

US3822015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:48:22
User entered '11 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:32:59

US3822015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:48:22
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:32:59

US3822015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:48:22
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:32:59

US3822015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:48:49
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:04

US3822015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:33:04

US3822015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:55:07
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:23

US3822015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:55:07
User entered '17 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:23

US3822015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:55:07
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:23

US3822015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:55:07
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:23

US3822015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:55:15
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:28

US3822015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:33:28

US3822015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:06:34
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:50

US3822015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:06:34
User entered '24 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:50

US3822015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:06:34
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:50

US3822015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:06:34
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:50

US3822015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:06:40
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:33:54

US3822015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:33:54

US3822015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:29:58
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:27:45

US3822015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:29:58
User entered '1 Oct 2020'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:27:45

US3822015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:29:58
User entered 'Clinic (Clinic)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:27:45

US3822015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:22:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Oct 2020 19:27:45

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '1 Oct 2020'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '11:43'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 11:43'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '98.2' F	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered 'Oral (Oral)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:29:10
	(b) (4)	

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '84'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '20'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '122'	Krishna Shah (b) (4)	05 Oct 2020 19:29:10
	(b) (4)	

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:31:17
User entered '80'	Krishna Shah (b) (4)	05 Oct 2020 19:29:10
	(b) (4)	

US3822015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:22:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 19:29:10

US3822015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO Physical Exam, please confirm and update PE findings to AEs or add to Med. History if applicable. Nasal Cannula, Bilateral Edema, Delayed Capillary Refill of Hands bilaterally.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:52:15
Query 'Per CRIO Physical Exam, please confirm and update PE findings to AEs or add to Med. History if applicable. Nasal Cannula, Bilateral Edema, Delayed Capillary Refill of Hands bilaterally.' answered with 'Nasal cannula has already been added to conmeds (only during hospitalization). Bilateral edema has been added (delayed capillary refill of hands is same as edema). ' (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 23:01:16
User opened query 'Per CRIO Physical Exam, please confirm and update PE findings to AEs or add to Med. History if applicable. Nasal Cannula, Bilateral Edema, Delayed Capillary Refill of Hands bilaterally.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:03:36
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:33:36
User entered 'Yes (Y)'	Krishna Shah (b) (4)	05 Oct 2020 19:29:30

US3822015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:22:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:33:36
User entered '1 Oct 2020'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:30

US3822015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:34:16
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:54

US3822015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:34:16
User entered '1 Oct 2020'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:54

US3822015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:34:16
User entered '11:51'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:29:54

US3822015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:22:22

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020 11:51'	System	05 Oct 2020 19:29:54

US3822015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User closed query 'Kindly add D85 to EDC as this was completed on 29OCT2020 per EMR. Thank yo.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:19:01
Query 'Kindly add D85 to EDC as this was completed on 29OCT2020 per EMR. Thank yo.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:10:01
User opened query 'Kindly add D85 to EDC as this was completed on 29OCT2020 per EMR. Thank yo.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:29:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 14:34:22
User entered 'Yes (Y)'	Krishna Shah (b) (4)	05 Oct 2020 19:27:51

US3822015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:27:51

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 64'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-08T18:00:02', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '2dce2e93-07b8-4242-9dd3-3c6f5e5beb77'	System	08 Oct 2020 22:00:33
User entered 'No (N)'	System	08 Oct 2020 22:00:33

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

Have you been exposed to someone with 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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-08T18:00:16', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '2dce2e93-07b8-4242-9dd3-3c6f5e5beb77'	System	08 Oct 2020 22:00:33
User entered 'No (N)'	System	08 Oct 2020 22:00:33

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-08T18:00:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '2dce2e93-07b8-4242-9dd3-3c6f5e5beb77'	System	08 Oct 2020 22:00:33
User entered '08 Oct 2020 18:00:29'	System	08 Oct 2020 22:00:33

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 71'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-12T06:36:54', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f0d5d2ce-d936-426f-bdf3-24b147416420'	System	12 Oct 2020 10:37:39
User entered 'No (N)'	System	12 Oct 2020 10:37:39

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

Have you been exposed to someone with 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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-12T06:37:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f0d5d2ce-d936-426f-bdf3-24b147416420'	System	12 Oct 2020 10:37:39
User entered 'No (N)'	System	12 Oct 2020 10:37:39

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-12T06:37:36', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f0d5d2ce-d936-426f-bdf3-24b147416420' User entered '12 Oct 2020 06:37:36'	System	12 Oct 2020 10:37:39
	System	12 Oct 2020 10:37:39

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 78'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-19T06:08:40', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f894e1c2-a21c-4016-9b52-f6fb4fa30bf7'	System	19 Oct 2020 10:09:21
User entered 'No (N)'	System	19 Oct 2020 10:09:21

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

Have you been exposed to someone with 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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-19T06:08:56', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f894e1c2-a21c-4016-9b52-f6fb4fa30bf7'	System	19 Oct 2020 10:09:21
User entered 'No (N)'	System	19 Oct 2020 10:09:21

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-10-19T06:09:17', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'f894e1c2-a21c-4016-9b52-f6fb4fa30bf7' User entered '19 Oct 2020 06:09:17'	System	19 Oct 2020 10:09:21

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 92'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-02T06:23:28', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9ed7e271-cfab-407a-ad4b-bb2abe138878'	System	02 Nov 2020 11:24:24
User entered 'No (N)'	System	02 Nov 2020 11:24:24

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

Have you been exposed to someone with 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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-02T06:23:46', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9ed7e271-cfab-407a-ad4b-bb2abe138878'	System	02 Nov 2020 11:24:24
User entered 'No (N)'	System	02 Nov 2020 11:24:24

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-02T06:24:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '9ed7e271-cfab-407a-ad4b-bb2abe138878' User entered '02 Nov 2020 06:24:22'	System	02 Nov 2020 11:24:24
	System	02 Nov 2020 11:24:24

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 99'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-09T06:30:11', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '709fcd18-42f9-4d3d-80ec-a2b972975b5a'	System	09 Nov 2020 11:30:56
User entered 'No (N)'	System	09 Nov 2020 11:30:56

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

Have you been exposed to someone with 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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-09T06:30:27', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '709fcd18-42f9-4d3d-80ec-a2b972975b5a'	System	09 Nov 2020 11:30:56
User entered 'No (N)'	System	09 Nov 2020 11:30:56

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-09T06:30:51', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '709fcd18-42f9-4d3d-80ec-a2b972975b5a' User entered '09 Nov 2020 06:30:51'	System	09 Nov 2020 11:30:56
	System	09 Nov 2020 11:30:56

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered 'Day 106'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-16T06:39:29', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '81888c8a-495b-43be-b0e9-e73ce5a2f090'	System	16 Nov 2020 11:40:10
User entered 'No (N)'	System	16 Nov 2020 11:40:10

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

Have you been exposed to someone with 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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-16T06:39:44', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '81888c8a-495b-43be-b0e9-e73ce5a2f090'	System	16 Nov 2020 11:40:10
User entered 'No (N)'	System	16 Nov 2020 11:40:10

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-16T06:40:07', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: '81888c8a-495b-43be-b0e9-e73ce5a2f090'	System	16 Nov 2020 11:40:10
User entered '16 Nov 2020 06:40:07'	System	16 Nov 2020 11:40:10

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 17:11:43

US3822015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 17:11:43
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 17:11:43

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Oct 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '06 Oct 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Oct 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '13 Oct 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-23T06:43:22', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd443aab9-b177-43de-9251-4a21eee0702b'	System	23 Nov 2020 11:44:20
User entered 'No (N)'	System	23 Nov 2020 11:44:20

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

Have you been exposed to someone with 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 (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-23T06:43:42', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd443aab9-b177-43de-9251-4a21eee0702b'	System	23 Nov 2020 11:44:20
User entered 'No (N)'	System	23 Nov 2020 11:44:20

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D6702EAB-395E-421D-8D44-845E94E81691)', Time: '2020-11-23T06:44:18', User OID: 'PatientReportedOutcome (US3822015)', ODM File OID: 'd443aab9-b177-43de-9251-4a21eee0702b' User entered '23 Nov 2020 06:44:18'	System	23 Nov 2020 11:44:20
	System	23 Nov 2020 11:44:20

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:30:34

US3822015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:30:34
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:30:34

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 01:09:27

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered '29 Oct 2020'	Kelly Woodell (b) (4)	05 Nov 2020 01:09:27
	(b) (4)	

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	05 Nov 2020 01:09:27

US3822015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:19:12
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:09:27

US3822015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:19:56
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 01:09:34

US3822015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 01:09:34

US3822015

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:22:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:53:22

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 18:55:16
User closed query 'Please ensure data entered in EDC is consistent with CRIO. CRIO AE Term "Heart Failure" in CRIO. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:22:16
Query 'Please ensure data entered in EDC is consistent with CRIO. CRIO AE Term "Heart Failure" in CRIO. ' answered with 'term updated' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	12 Oct 2020 15:18:32
User opened query 'Please ensure data entered in EDC is consistent with CRIO. CRIO AE Term "Heart Failure" in CRIO. ' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 19:47:19
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:38:54
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:25
User entered 'USA-US126-2020-mRNA-1273-P301000002'	System	12 Sep 2020 18:50:43
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 18:50:43

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 14:21:59
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 15:20:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	12 Oct 2020 15:20:15
Data point term sent to Coder	System	12 Oct 2020 15:19:34
Coding entries removed.	Kelly Woodell (b) (4)	12 Oct 2020 15:18:43
User entered 'Heart Failure' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 15:18:43
User closed query 'PV Query: The reported event term hypoxemia is a symptom. Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 14:03:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 19:36:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	05 Oct 2020 19:36:22
Data point term sent to Coder	System	05 Oct 2020 19:35:50
Query 'PV Query: The reported event term hypoxemia is a symptom. Please consider updating the event term to the underlying cause/etiology of the event. ' answered with 'updated ' (Site from Safety).	Krishna Shah (b) (4)	05 Oct 2020 19:35:50
DataPoint Un-verified.	(b) (4)	05 Oct 2020 19:35:30
Coding entries removed.	Krishna Shah (b) (4)	05 Oct 2020 19:35:30
User entered 'Pleural effusion' reason for change: Data Entry Error	(b) (4)	05 Oct 2020 19:35:30
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User opened query 'PV Query: The reported event term hypoxemia is a symptom. Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:12:03

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:58:45
Data point term sent to Coder	System	11 Sep 2020 17:57:11
User entered 'Hypoxemia'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 14:22:41
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (09 Sep 2020). If not updating the start date, please clarify.' (Site from Safety). Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (09 Sep 2020). If not updating the start date, please clarify.' answered with 'date updated per query' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 15:29:16
User entered '09 Sep 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	08 Oct 2020 14:34:40
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (09 Sep 2020). If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 14:34:22
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (09 Sep 2020). If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 15:00:19
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (09 Sep 2020). If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 14:28:09
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (09 Sep 2020). If not updating the start date, please clarify.' answered with 'This is the date provided by patient of when symptoms started.' (Site from Safety).	Krishna Shah (b) (4)	28 Sep 2020 21:29:38
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 14:12:15
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (09 Sep 2020). If not updating the start date, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:15:00
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:17:13
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 14:16:48
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 18:03:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:03:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 17:58:11
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:58:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 17:57:10
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 17:57:10
User entered '24:00' (non-conformant).	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:03:06
User entered '10 Sep 2020 00:00'	System	11 Sep 2020 17:58:11
User entered '10 Sep 2020 24:00' (non-conformant).	System	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per Source the end date is noted as 12SEP2020. Please review and update End Date if applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 13:31:35
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 13:31:32
Query 'Per Source the end date is noted as 12SEP2020. Please review and update End Date if applicable.' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4)	28 Sep 2020 21:31:08
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 21:30:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 21:30:28
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Sep 2020 21:29:54
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 21:29:54
User opened query 'Per Source the end date is noted as 12SEP2020. Please review and update End Date if applicable.' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 14:15:17
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:01:02
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated ' (Site from System).	Krishna Shah (b) (4)	05 Oct 2020 19:36:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 13:31:50
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Sep 2020 21:31:48
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Sep 2020 21:31:48
DataPoint Un-verified.	Krishna Shah (b) (4)	28 Sep 2020 21:31:48
	(b) (4)	
User entered '12 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 21:31:48
	(b) (4)	
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Sep 2020 21:30:53
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Sep 2020 21:30:28
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Sep 2020 21:29:54
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Sep 2020 22:47:41
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	16 Sep 2020 22:47:41
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Sep 2020 22:44:10
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[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)	06 Oct 2020 14:04:05
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)	17 Sep 2020 19:13:28
User entered empty.	System	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Severity

Audit	User	Time (GMT)
User closed query 'Per CRIO intensity is Moderate. Please review and update CRIO or EDC as applicable.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	22 Oct 2020 14:23:08
	(b) (4), (b) (6) (b) (4)	22 Oct 2020 14:23:05
Query 'Per CRIO intensity is Moderate. Please review and update CRIO or EDC as applicable.' answered with 'EDC updated to match CRIO' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	12 Oct 2020 12:18:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	12 Oct 2020 12:17:43
User opened query 'Per CRIO intensity is Moderate. Please review and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	08 Oct 2020 19:48:18
User closed query 'PV Query: As the event required hospitalization, please consider updating intensity to grade 3. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	06 Oct 2020 14:04:07
Query 'PV Query: As the event required hospitalization, please consider updating intensity to grade 3. If not, please clarify.' answered with 'updated ' (Site from Safety).	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:36:01
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:30:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:30:53
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	22 Sep 2020 14:08:53
User opened query 'PV Query: As the event required hospitalization, please consider updating intensity to grade 3. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	17 Sep 2020 19:14:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6) (b) (4)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
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)	14 Sep 2020 10:36:50
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 'Patient has not been discharged yet. ' (Site from System).	Krishna Shah (b) (4) (b) (4)	11 Sep 2020 19:09:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Sep 2020 17:57:10
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 14:04:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:14:16
User entered '09 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 14:04:14
	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User closed query 'Per CDM: Please provide Discharge date. Kindly keep the query open until information is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 09:23:10
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:15:43
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:12:46
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:12:36
Query 'Per CDM: Please provide Discharge date. Kindly keep the query open until information is available. Thank you.' answered with 'date added' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:47:51
User entered '12 Sep 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	16 Sep 2020 22:44:10
User opened query 'Per CDM: Please provide Discharge date. Kindly keep the query open until information is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 15:11:10
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 14:23:26
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 03 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 14:04:19
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 03 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated ' (Site from Safety).	Krishna Shah (b) (4)	05 Oct 2020 19:36:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Krishna Shah (b) (4)	05 Oct 2020 19:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	22 Sep 2020 14:16:31
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 03 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:14:45
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query '. PV Query: Please add concomitant medications received within 30days prior to the event (or > 30 days if relevant to the event) to medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none given to patient than state so. ' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 14:04:25
Query '. PV Query: Please add concomitant medications received within 30days prior to the event (or > 30 days if relevant to the event) to medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none given to patient than state so. ' answered with 'updated ' (Site from Safety).	Krishna Shah (b) (4)	05 Oct 2020 19:41:09
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User opened query '. PV Query: Please add concomitant medications received within 30days prior to the event (or > 30 days if relevant to the event) to medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none given to patient than state so. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:12:23
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 14:23:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 14:04:28
DataPoint Un-verified.	Krishna Shah (b) (4)	05 Oct 2020 19:41:38
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Krishna Shah (b) (4)	05 Oct 2020 19:41:38
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:13:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	16 Sep 2020 22:47:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	16 Sep 2020 22:44:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 14:23:41
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	08 Oct 2020 14:41:08
DataPoint Un-verified.	Kelly Woodell (b) (4)	08 Oct 2020 14:41:08
User entered 'Continuing on oxygen' reason for change: Data Entry Error	Kelly Woodell (b) (4)	08 Oct 2020 14:41:08
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	05 Oct 2020 19:41:38
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:57:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:39:36
User closed query 'Per DM CLR: SAE Narrative indicates that subject received Lasix as treatment. However, there are no corresponding Concomitant Medications record that match this information. Please update to record the corresponding treatments accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:52:26
Query 'Per CDM: Please provide location of update such as log line number. Thank you.' answered with 'Line 5, 6 and 7' (Site from DM).	Kelly Woodell (b) (4)	10 Nov 2020 16:56:33
User opened query 'Per CDM: Please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:43:44
User closed query 'Per DM CLR: SAE Narrative indicates that the subject had Ablation for Atrial Fibrillation, and the patient also underwent and Echocardiogram and is working with an Incentive Spirometer. However, there are no corresponding Concomitant Procedures record that match this information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:42:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:17:18
User closed query 'Per narrative, lasix is still noted, should this be updated?' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:17:14
Query 'Per narrative, lasix is still noted, should this be updated?' answered with 'narrative updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:32:23
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:32:16

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD PLANNED OUTPATIENT ABLATION FOR PERMANENT ATRIAL FIBRILLATION ON 9SEP20. HE FELT WELL BUT DURING THE NIGHT HE DEVELOPED SHORTNESS OF BREATH, CHEST DISCOMFORT AND WAS FOUND TO BE HYPOXIC. A CHEST X-RAY FOUND NEW MILD RIGHT PLEURAL EFFUSION. HE WAS GIVEN OXYGEN. AN ECHO WAS PERFORMED WHICH SHOWED A DECREASED EJECTION FRACTION AS COMPARED TO PREVIOUS TEST. HE IS CONTINUING TO RECEIVE OXYGEN AND IS WORKING WITH INCENTIVE SPIROMETER. HE IS ABLE TO GET UP AND MOVE AROUND WITH ASSISTANCE. SYMPTOMS RESOLVING WITH OXYGEN.'	Kelly Woodell (b) (4)	05 Nov 2020 00:32:16
reason for change: Data Entry Error		
User opened query 'Per narrative, lasix is still noted, should this be updated?' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:48:38
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User closed query 'PV Query: Please add cardiac ablation and biotronic pacemaker insertion for sinus node dysfunction and chronotropic incompetence to subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 18:55:08
Query 'PV Query: Please add cardiac ablation and biotronic pacemaker insertion for sinus node dysfunction and chronotropic incompetence to subject's medical history.' answered with 'added' (Site from Safety).	Kelly Woodell (b) (4)	22 Oct 2020 18:13:56
Query 'Per DM CLR: SAE Narrative indicates that subject received Lasix as treatment. However, there are no corresponding Concomitant Medications record that match this information. Please update to record the corresponding treatments accordingly. Otherwise, clarify.' answered with 'updated narrative to remove lasix as it was not listed in the discharge summary' (Site from DM).	Kelly Woodell (b) (4)	22 Oct 2020 18:12:49
DataPoint Un-verified.	Kelly Woodell (b) (4)	22 Oct 2020 18:12:32

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD PLANNED OUTPATIENT ABLATION FOR PERMANENT ATRIAL FIBRILLATION ON 9SEP20. HE FELT WELL BUT DURING THE NIGHT HE DEVELOPED SHORTNESS OF BREATH, CHEST DISCOMFORT AND WAS FOUND TO BE HYPOXIC. A CHEST X-RAY FOUND NEW MILD RIGHT PLEURAL EFFUSION. HE WAS GIVEN OXYGEN. AN ECHO WAS PERFORMED WHICH SHOWED A DECREASED EJECTION FRACTION AS COMPARED TO PREVIOUS TEST. HE IS CONTINUING TO RECEIVE OXYGEN AND IS WORKING WITH INCENTIVE SPIROMETER. HE IS ABLE TO GET UP AND MOVE AROUND WITH ASSISTANCE. SYMPTOMS RESOLVING WITH THE LASIX AND OXYGEN.' reason for change: Data Entry Error	Kelly Woodell (b) (4)	22 Oct 2020 18:12:32
Query 'Per DM CLR: SAE Narrative indicates that the subject had Ablation for Atrial Fibrillation, and the patient also underwent and Echocardiogram and is working with an Incentive Spirometer. However, there are no corresponding Concomitant Procedures record that match this information. Please update to record the procedures as appropriate. Otherwise, clarify.	Kelly Woodell (b) (4)	22 Oct 2020 18:11:43
' answered with 'added' (Site from DM). User opened query 'PV Query: Please add cardiac ablation and biotronic pacemaker insertion for sinus node dysfunction and chronotropic incompetence to subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:09:31
User opened query 'Per DM CLR: SAE Narrative indicates that subject received Lasix as treatment. However, there are no corresponding Concomitant Medications record that match this information. Please update to record the corresponding treatments accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:44:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative indicates that the subject had Ablation for Atrial Fibrillation, and the patient also underwent and Echocardiogram and is working with an Incentive Spirometer. However, there are no corresponding Concomitant Procedures record that match this information. Please update to record the procedures as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:44:41
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:50:22
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:19:20
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 12:58:28
User closed query 'Per DM CLR: SAE Narrative indicates that a Right Pleural Effusion was noted on Chest X-ray and a Decreased Ejection Fraction noted from Echocardiogram. However, there are no corresponding AE record that match the findings. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:44:15
User closed query 'Per DM CLR: SAE Narrative indicates that a Cardiac Ablation, Chest X Ray, Echocardiogram and Incentive Spirometer were the procedures performed for this SAE. However, there are not corresponding Concomitant Procedures record that match the mentioned procedures. Please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:43:54

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative indicates Oxygen and Lasix were given as treatment. However, there are no corresponding Concomitant Medication record that match the medications. Please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:31:49
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary emailed 10/12/2020 @ 11:18 am' (Site from Safety).	Kelly Woodell (b) (4)	12 Oct 2020 15:18:06
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 15:29:09
Query 'Per DM CLR: SAE Narrative indicates that a Right Pleural Effusion was noted on Chest X-ray and a Decreased Ejection Fraction noted from Echocardiogram. However, there are no corresponding AE record that match the findings. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'added' (Site from DM).	Kelly Woodell (b) (4)	08 Oct 2020 14:58:35
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no testing noted in discharge summary' (Site from Safety).	Kelly Woodell (b) (4)	08 Oct 2020 14:42:08
Query 'Per DM CLR: SAE Narrative indicates that a Cardiac Ablation, Chest X Ray, Echocardiogram and Incentive Spirometer were the procedures performed for this SAE. However, there are not corresponding Concomitant Procedures record that match the mentioned procedures. Please update to record accordingly. Otherwise, clarify.' answered with 'added' (Site from DM).	Kelly Woodell (b) (4)	08 Oct 2020 14:41:38

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative indicates Oxygen and Lasix were given as treatment. However, there are no corresponding Concomitant Medication record that match the medications. Please update to record accordingly. Otherwise, clarify.' answered with 'added' (Site from DM).	Kelly Woodell (b) (4)	08 Oct 2020 14:41:21
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 15:00:51
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:59:37
Query 'PV query: Please provide the results of the echocardiogram done. ' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 14:04:37
Query 'PV Query: If available, please provide specific relevant laboratory results, enzyme tests, ECG results, etc. with dates performed, units and reference ranges. ' canceled (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 14:04:35
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:08:53
User opened query 'Per DM CLR: SAE Narrative indicates that a Right Pleural Effusion was noted on Chest X-ray and a Decreased Ejection Fraction noted from Echocardiogram. However, there are no corresponding AE record that match the findings. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 16:06:14
User opened query 'Per DM CLR: SAE Narrative indicates that a Cardiac Ablation, Chest X Ray, Echocardiogram and Incentive Spirometer were the procedures performed for this SAE. However, there are not corresponding Concomitant Procedures record that match the mentioned procedures. Please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 16:05:50

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative indicates Oxygen and Lasix were given as treatment. However, there are no corresponding Concomitant Medication record that match the medications. Please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 16:04:26
User opened query 'PV query: Please provide the results of the echocardiogram done. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:15:59
User opened query 'PV Query: If available, please provide specific relevant laboratory results, enzyme tests, ECG results, etc. with dates performed, units and reference ranges. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 19:14:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 19:35:25
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 19:35:25
User entered 'Patient had planned outpatient ablation for permanent atrial fibrillation on 9Sep20. He felt well but during the night he developed shortness of breath, chest discomfort and was found to be hypoxic. A chest x-ray found new mild right pleural effusion. He was given Oxygen and Lasix. An ECHO was performed which showed a decreased ejection fraction as compared to previous test. He is continuing to receive oxygen and is working with incentive spirometer. He is able to get up and move around with assistance. Symptoms resolving with the Lasix and Oxygen.' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	11 Sep 2020 19:35:25
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 17:57:10
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:22:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 17:57:10

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:23:28
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection ' answered with 'Patient confirmed no COVID-10 test was done during hospitalization. ' (Site from DM).	Krishna Shah (b) (4)	17 Nov 2020 20:02:31
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:39:44
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:25:04
User closed query 'Please add AE to CRIO Source Documentation.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:22:42
Query 'Please add AE to CRIO Source Documentation.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	22 Oct 2020 17:53:40
User opened query 'Please add AE to CRIO Source Documentation.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:26:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 22:54:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 22:54:25
Data point term sent to Coder	System	08 Oct 2020 15:01:05
User entered 'Right pleural effusion'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:32:11
User entered 'No (N)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:31:38
User entered 'No (N)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:32:16
User entered 'No (N)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:26:52
User entered '11 Sep 2020'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:32:18
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Oct 2020 15:01:23
User entered empty; reason for change Data Entry Error	Kelly Woodell (b) (4)	08 Oct 2020 15:01:23
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Oct 2020 15:00:54
User entered '13:36'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:01:23
User entered '11 Sep 2020 13:36'	System	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:50:02
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 13:31:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:31:09
User closed query 'Per MM, Please provide end date.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:26:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:00:51
Query 'Per MM, Please provide end date.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4)	17 Nov 2020 20:02:57
DataPoint Un-verified.	(b) (4)	
	Krishna Shah (b) (4)	17 Nov 2020 20:02:50
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4)	17 Nov 2020 20:02:50
	(b) (4)	
User opened query 'Per MM, Please provide end date.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:39:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:32:19
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54
	(b) (4)	

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:50:05
User closed query 'Per CRIO Source, AE is Ongoing. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:49:56
Query 'Per CRIO Source, AE is Ongoing. Please reconcile and update CRIO or EDC as applicable.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 13:32:00
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 13:31:53
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Nov 2020 13:31:53
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Nov 2020 13:31:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:31:09
User opened query 'Per CRIO Source, AE is Ongoing. Please reconcile and update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:07:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 20:03:06
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	17 Nov 2020 20:03:06
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 20:02:50
DataPoint Un-verified.	Krishna Shah (b) (4)	17 Nov 2020 20:02:50
User entered '12 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	17 Nov 2020 20:02:50
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:37

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:44:46
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:06:05
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:43
User entered empty.	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:41
User entered 'No (N)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:45
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 03 Sept 2020 and AE#2 has a start date 11 Sept 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:25:15
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 03 Sept 2020 and AE#2 has a start date 11 Sept 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 18:55:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 18:55:30
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 03 Sept 2020 and AE#2 has a start date 11 Sept 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:36:00
User entered 'None (NONE)'	Kelly Woodell (b) (4) (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '1'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered '0'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:47:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 13:31:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:31:53
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:44:58
DataPoint Un-verified.	Krishna Shah (b) (4)	17 Nov 2020 20:03:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Krishna Shah (b) (4)	17 Nov 2020 20:03:06
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:33:48
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:22:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 15:00:54

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:10
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema legs - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 21:05:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 21:05:50
Data point term sent to Coder	System	17 Nov 2020 20:04:39
User closed query 'For coding purposes, please clarify/provide more information for term BILATERAL EDEMA. Is this BILATERAL EDEMA Lower extremities or BILATERAL EDEMA Upper extremities or something else.' (Site from System).	System	17 Nov 2020 20:03:57
Query 'For coding purposes, please clarify/provide more information for term BILATERAL EDEMA. Is this BILATERAL EDEMA Lower extremities or BILATERAL EDEMA Upper extremities or something else.' answered with 'updated' (Site from System).	Krishna Shah (b) (4)	17 Nov 2020 20:03:57
DataPoint Un-verified.	Krishna Shah (b) (4)	17 Nov 2020 20:03:49
User entered 'BILATERAL EDEMA, legs' reason for change: Data Entry Error	Krishna Shah (b) (4)	17 Nov 2020 20:03:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User opened query 'For coding purposes, please clarify/provide more information for term BILATERAL EDEMA. Is this BILATERAL EDEMA Lower extremities or BILATERAL EDEMA Upper extremities or something else.' (Site from System).	Coder Import (b) (4)	10 Nov 2020 10:32:29
Data point term sent to Coder	System	06 Nov 2020 23:01:26
User entered 'Bilateral Edema'	Krishna Shah (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '10 Sep 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '12 Sep 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4)	06 Nov 2020 23:01:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4)	06 Nov 2020 23:01:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4)	06 Nov 2020 23:01:12
	(b) (4)	

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4)	06 Nov 2020 23:01:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'Not Related (NOT RELATED)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'Not Applicable (NOT APPLICABLE)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4)	06 Nov 2020 23:01:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '1'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered '0'	Krishna Shah (b) (4)	06 Nov 2020 23:01:12
	(b) (4)	

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:59
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 23:01:12

US3822015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:22:22

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 23:01:12

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:22:22

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO, please add the following concomitant medications, if applicable: Tylenol PM Metoprolol Omeprazole ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:21:56
Query 'Per CRIO, please add the following concomitant medications, if applicable: Tylenol PM Metoprolol Omeprazole ' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:07:13
User opened query 'Per CRIO, please add the following concomitant medications, if applicable: Tylenol PM Metoprolol Omeprazole ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 17:48:46
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:52:44
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:12:29

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:14:44
Data point term sent to Coder	System	28 Sep 2020 21:13:25
User entered 'amlodipine'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:40
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:42
User entered 'hypertension'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:44
User entered '5'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:46
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:48
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:50
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:53
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:55
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:07:57
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:18:19
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:32:47
User entered 'un UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:32:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 15:07:59
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 21:13:17
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:18:28
User closed query 'Per CRIO, Start Date of 2018. Please reconcile and update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:18:25
Query 'Per CRIO, Start Date of 2018. Please reconcile and update EDC if applicable.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:32:52
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:32:47
User entered '0' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:32:47
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:08:01
User opened query 'Per CRIO, Start Date of 2018. Please reconcile and update EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:07:22
User entered '1'	Krishna Shah (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:08:02
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:08:04
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:08:06
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 21:13:17

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:11:36
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) (b) (4)	28 Sep 2020 21:15:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:15:45
Data point term sent to Coder	System	28 Sep 2020 21:14:27
User entered 'eliquis'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per CRIO prophylaxis is no; however indication in CRIO notes cardiac prophylaxis. Please review both prophylaxis and the indication and update EDC or CRIO as applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:18:56
User opened query 'Per CRIO prophylaxis is no; however indication in CRIO notes cardiac prophylaxis. Please review both prophylaxis and the indication and update EDC or CRIO as applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:15:50
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:11:51
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:11:52
User entered 'cardiac health'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:11:59
User entered '5'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:12:01
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:12:08
User entered 'twice daily (BID)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:12:10
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CRIO start date is December 2019, please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:18:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:18:45
Query 'Per CRIO start date is December 2019, please reconcile and update if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:33:18
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:33:11
User entered 'UN Dec 2019' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:33:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User opened query 'Per CRIO start date is December 2019, please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:16:49
User entered 'UN May 2020'	Krishna Shah (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 21:14:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please reconcile Indication and Route of Administration' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:46:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:54:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:54:29
Query 'Per MM, Please reconcile Indication and Route of Administration' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 18:53:39
Data point term sent to Coder	System	19 Oct 2020 18:53:34
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 18:53:15
User opened query 'Per MM, Please reconcile Indication and Route of Administration' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 19:23:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:17:49
Data point term sent to Coder	System	28 Sep 2020 21:16:30
User entered 'fluticasone propionate'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
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) (6)	10 Nov 2020 04:45:10
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 'updated' (Site from DM).	Kelly Woodell (b) (4)	05 Nov 2020 00:34:15
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)	23 Oct 2020 02:34:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'allergic rhinitis'	Krishna Shah (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '50'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'ug (ug)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:19:25
User closed query 'Per CRIO, frequency is noted as once daily. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:19:20
Query 'Per CRIO, frequency is noted as once daily. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:34:19
DataPoint Un-verified.	(b) (4)	05 Nov 2020 00:34:04
User entered 'once daily (QD)' reason for change:	Kelly Woodell (b) (4)	05 Nov 2020 00:34:04
Data Entry Error	(b) (4)	
User opened query 'Per CRIO, frequency is noted as once daily. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:24:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'twice daily (BID)'	Krishna Shah (b) (4)	28 Sep 2020 21:15:42
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 18:53:15
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CRIO, start date is 2018, please review and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:19:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:19:33
Query 'Per CRIO, start date is 2018, please review and update if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:34:25
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:33:57
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:33:57
User opened query 'Per CRIO, start date is 2018, please review and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:22:02
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN UNK 2020'	Krishna Shah (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4)	28 Sep 2020 21:25:47
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		28 Sep 2020 21:25:47
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		28 Sep 2020 21:15:42
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 00:34:04
User entered '2'	System	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 21:15:42

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:17:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:17:46
Data point term sent to Coder	System	28 Sep 2020 21:17:34
User entered 'gabapentin'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'peripheral nerve disease'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '300'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'twice daily (BID)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN UNK 2018'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 21:16:54

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:45:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:45:52
Data point term sent to Coder	System	28 Sep 2020 21:18:35
User entered 'Lisinopril'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'hypertension'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '40'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN UNK 2018'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 21:17:41

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:42:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:42:44
Data point term sent to Coder	System	28 Sep 2020 21:19:36
User entered 'Metoprolol succinate ER'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'VENTRICULAR PREMATURE BEATS'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '50'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'once daily (QD)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:20:05
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:20:01
Query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:36:08
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:36:05
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:36:05
User opened query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:39:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN UNK 2019'	Krishna Shah (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 21:18:48

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 00:38:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:38:38
Data point term sent to Coder Coding entries removed.	System Kelly Woodell (b) (4)	05 Nov 2020 00:37:56 05 Nov 2020 00:37:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:17:43
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) (b) (4)	28 Sep 2020 21:22:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:22:06
Data point term sent to Coder User entered 'tamsulosin'	System Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:40 28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 07:45:48
	(b) (4), (b) (6)	05 Nov 2020 15:20:45
User closed query 'Kindly spell out indication. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:20:42
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 'added' (Site from DM).	Kelly Woodell (b) (4)	05 Nov 2020 00:45:53
Query 'Kindly spell out indication. Thank you.' answered with 'updated' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:37:08
	(b) (4)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:37:00
	(b) (4)	
User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:37:00
	(b) (4)	
User opened query 'Kindly spell out indication. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:14:12
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)	23 Oct 2020 02:35:04
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'BPH'	Krishna Shah (b) (4)	28 Sep 2020 21:20:02
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0.4'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'twice daily (BID)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:21:02
User closed query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:20:59
Query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:37:11
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:37:00
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:37:00
User opened query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:41:41
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN UNK 2020'	Krishna Shah (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 21:20:02

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:57:35
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 00:57:35
Data point term sent to Coder Coding entries removed.	System Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:57:13 05 Nov 2020 00:56:19
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:22:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:22:55
Data point term sent to Coder User entered 'testosterone cypionate'	System Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:43 28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'hypogonadism'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '200'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'as needed (PRN)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:29:13
User closed query 'Per CRIO, dose route is noted as topical. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:29:10
Query 'Per CRIO, dose route is noted as topical. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:56:32
DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:56:19
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:56:19
User opened query 'Per CRIO, dose route is noted as topical. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:51:36
Query 'Per CRIO, dose form is noted as ointment. Please review and reconcile if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:51:01
User opened query 'Per CRIO, dose form is noted as ointment. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:49:56
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:29:23
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:29:19
Query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:56:35
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:56:19
User entered 'UN UNK 2018' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:56:19
User opened query 'Per CRIO, start date is noted as 2018. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:52:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN UNK 2020'	Krishna Shah (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:20:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 01:00:40
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 01:00:40
Data point term sent to Coder Coding entries removed.	System Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:59:15 05 Nov 2020 00:58:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:22:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:22:49
Data point term sent to Coder User entered 'tylenol'	System Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:47 28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO, reason is noted as unknown. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:29:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:29:42
Query 'Per CRIO, reason is noted as unknown. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:58:58
DataPoint Un-verified.	(b) (4)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:58:53
User entered 'Unknown' reason for change: Data Entry Error	(b) (4)	
	Kelly Woodell (b) (4)	05 Nov 2020 00:58:53
User opened query 'Per CRIO, reason is noted as unknown. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:03:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'pain'	Krishna Shah (b) (4)	28 Sep 2020 21:21:25
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO, dose is noted as 500. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:29:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:29:49
Query 'Per CRIO, dose is noted as 500. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:59:01
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:58:53
User entered '500' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:58:53
User opened query 'Per CRIO, dose is noted as 500. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:06:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'unk'	Krishna Shah (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
Query 'Per CRIO, dose is noted as 500mg. Please review and reconcile if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:05:41
User opened query 'Per CRIO, dose is noted as 500mg. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:05:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mg (mg)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO, frequency is noted as twice daily. Please review and reconcile if applicable.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Nov 2020 15:30:02
Query 'Per CRIO, frequency is noted as twice daily. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4)	05 Nov 2020 15:29:58
User entered 'twice daily (BID)' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:59:03
User opened query 'Per CRIO, frequency is noted as twice daily. Please review and reconcile if applicable.' (Site from CRA). DataPoint Verified.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:58:53
User entered 'as needed (PRN)'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 00:58:53
	(b) (4), (b) (6) (b) (4)	21 Oct 2020 16:06:32
	(b) (4), (b) (6) (b) (4)	21 Oct 2020 15:17:43
	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Oral (ORAL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CRIO, start date is noted as 2020. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:30:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:08
Query 'Per CRIO, start date is noted as 2020. Please review and reconcile if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 00:59:07
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 00:58:53
User entered 'UN UNK 2020' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 00:58:53
User opened query 'Per CRIO, start date is noted as 2020. Please review and reconcile if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:07:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN UNK 2019'	Krishna Shah (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 00:58:53
User entered empty.	System	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 00:58:53
User entered empty.	System	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 00:58:53
User entered empty.	System	28 Sep 2020 21:21:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add Influenza vaccine to CRIO source documentation.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:30:44
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:40
Query 'Please add Influenza vaccine to CRIO source documentation.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:01:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:22:57
User opened query 'Please add Influenza vaccine to CRIO source documentation.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 17:39:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 21:24:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 21:24:06
Data point term sent to Coder	System	28 Sep 2020 21:22:48
User entered 'Influenza'	Krishna Shah (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:02
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '.5' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:01:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:38:06
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:08
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:12
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:20
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:27
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN Sep 2019'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:33
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:34
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN Sep 2019'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:38:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:22:06

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 15:31:08 05 Nov 2020 15:30:52
Query 'Please add Pneumococcal vaccine to CRIO source documentation.' answered with 'added' (Site from CRA). DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4) (b) (4), (b) (6)	05 Nov 2020 01:01:36 21 Oct 2020 17:40:54
User opened query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 17:40:51 21 Oct 2020 15:17:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE 13V - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:24:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:24:59
Data point term sent to Coder	System	28 Sep 2020 21:23:51
User entered 'Pneumococcal PCV 13'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:40:55
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:40:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:40:59
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:04
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:06
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:07
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:13
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '4 May 2016'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:16
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:21
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '4 May 2016'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:41:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:23:01

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 15:33:25 05 Nov 2020 15:30:52
Query 'Please add Pneumococcal vaccine to CRIO source documentation.' answered with 'added' (Site from CRA). DataPoint Un-verified.	Kelly Woodell (b) (4) (b) (4) (b) (4), (b) (6)	05 Nov 2020 01:02:33 21 Oct 2020 17:42:57
User opened query 'Please add Pneumococcal vaccine to CRIO source documentation.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 17:42:55 21 Oct 2020 15:17:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:26:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:26:07
Data point term sent to Coder	System	28 Sep 2020 21:24:52
User entered 'pneumococcal PPV 23'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:03
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:02
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:00
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:15
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:17
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:19
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:21
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '7 Apr 2015'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '7 Apr 2015'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:43:30
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:23:56

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Please add Zoster vaccine to CRIO source documentation.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:33:46
	(b) (4), (b) (6)	05 Nov 2020 15:30:52
Query 'Please add Zoster vaccine to CRIO source documentation.' answered with 'added' (Site from CRA). DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 01:03:19
	(b) (4), (b) (6)	21 Oct 2020 17:44:10
User opened query 'Please add Zoster vaccine to CRIO source documentation.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:08
	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ZOSTER - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 21:26:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 21:26:10
Data point term sent to Coder	System	28 Sep 2020 21:24:54
User entered 'zoster'	Krishna Shah (b) (4)	28 Sep 2020 21:24:51
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:13
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'vaccine'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:14
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:16
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'mL (mL)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:21
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'once (ONCE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:24
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:27
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:28
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN Oct 2018'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:30
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:34
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'UN Oct 2018'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 17:44:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:24:51

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:06:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:06:48
Data point term sent to Coder	System	06 Nov 2020 22:57:18
Data point term sent to Coder	System	05 Nov 2020 01:04:19
Coding entries removed.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:04:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
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.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:37:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:37:28
Data point term sent to Coder	System	05 Oct 2020 19:38:58
User entered 'oxygen'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO, indication is heart failure. Please review and reconcile, if applicable.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:34:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
Query 'Per CRIO, indication is heart failure. Please review and reconcile, if applicable.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:04:47
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Nov 2020 01:04:09
User entered 'Heart failure' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:04:09
User opened query 'Per CRIO, indication is heart failure. Please review and reconcile, if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 17:52:08
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'pleural effusion'	Krishna Shah (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '2'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Other (OTHER)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Liters'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'other (OTHER)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'continuous pump'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:46:28
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4)	06 Nov 2020 22:56:40
DataPoint Un-verified.	Krishna Shah (b) (4)	06 Nov 2020 22:56:33
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Krishna Shah (b) (4)	06 Nov 2020 22:56:33
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:06:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Nasal (NASAL)'	Krishna Shah (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '10 Sep 2020'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query ' Per discharge summary it is mentioned subject left with Lasix, kindly update EDC and ensure all con meds from AE/SAE of hospitalization are noted in EDC. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:18:21
Query ' Per discharge summary it is mentioned subject left with Lasix, kindly update EDC and ensure all con meds from AE/SAE of hospitalization are noted in EDC. Thank you. ' answered with 'updated ' (Site from CRA).	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:56:49
User opened query ' Per discharge summary it is mentioned subject left with Lasix, kindly update EDC and ensure all con meds from AE/SAE of hospitalization are noted in EDC. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:39:44
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 19:38:25

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:46:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:46:35
Data point term sent to Coder	System	05 Nov 2020 01:13:22
User entered 'Tylenol PM'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Obstructive sleep apnea syndrome'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '500'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'mg (mg)'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'once daily (QD)'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'un UNK 2019'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 01:13:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:07:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:07:56
Data point term sent to Coder	System	05 Nov 2020 01:14:22
User entered 'Metoprolol'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Cardiac ablation'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '25'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'mg (mg)'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'once daily (QD)'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '09 Sep 2020'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 01:14:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:21:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:21:11
Data point term sent to Coder	System	23 Nov 2020 15:19:09
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 15:18:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 01:18:34
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 01:18:34
Data point term sent to Coder	System	05 Nov 2020 01:17:23
User entered 'omeprazole'	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:47:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:18:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:18:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:47:55
Query 'Per CDM: Kindly Record the reason(Indication) the medication was taken based on clinical investigator's evaluation. Thank you!' answered with 'Per hospital discharge summary patient is taking omeprazole x 4 weeks for GI prophylaxis' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:20:42
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 15:18:48
User entered 'GI Prophyaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:18:48
User opened query 'Per CDM: Kindly Record the reason(Indication) the medication was taken based on clinical investigator's evaluation. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 03:47:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 03:47:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
Query 'Data is required. Please complete.' answered with 'Confirming indication as what is listed in source does not seem correct. Will update once confirmed.' (Site from System).	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:17:28
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 01:17:00
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '20'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'mg (mg)'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'twice daily (BID)'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Oral (ORAL)'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4) (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '09 Sep 2020'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered '0'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered empty.	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:30:52
User entered 'No (N)'	Kelly Woodell (b) (4)	05 Nov 2020 01:17:00
	(b) (4)	

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 01:17:00

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:28
Data point term sent to Coder	System	06 Nov 2020 23:02:28
Data point term sent to Coder	System	06 Nov 2020 22:54:14
User entered 'Lasix'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'Bilateral Edema' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 23:01:29
User entered 'Edema due to heart failure'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'unk'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'Other (OTHER)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'unknown'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'as needed (PRN)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'Intravenous (INTRAVENOUS)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered empty.	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered '10 Sep 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered '0'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered '12 Sep 2020'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:43
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:53:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:22:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CRIO_Was Treatment Required and PI Comments both mention use of Lasix. Please update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:45:04
Query 'Per CRIO_Was Treatment Required and PI Comments both mention use of Lasix. Please update CRIO or EDC as applicable.' answered with 'updated' (Site from CRA).	Krishna Shah (b) (4)	06 Nov 2020 22:53:59
User opened query 'Per CRIO_Was Treatment Required and PI Comments both mention use of Lasix. Please update CRIO or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:33:02
User closed query 'Please add Lasix to both EDC and CRIO if applicable.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:33:02
Query 'Please add Lasix to both EDC and CRIO if applicable.' answered with 'Per discharge summary there is no mention of Lasix' (Site from CRA).	Kelly Woodell (b) (4)	12 Oct 2020 16:53:04
User opened query 'Please add Lasix to both EDC and CRIO if applicable.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 19:57:03
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:56:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	08 Oct 2020 14:50:53
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 21:34:07

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '11 Sep 2020'	Kelly Woodell (b) (4)	08 Oct 2020 14:54:47
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'CT angiography coronary artery scan'	Kelly Woodell (b) (4)	08 Oct 2020 14:54:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4)	08 Oct 2020 14:54:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:22:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 14:54:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '11 Sep 2020'	Kelly Woodell (b) (4)	08 Oct 2020 14:55:20
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'CT Coronary Chest Noncardiac with Contrast'	Kelly Woodell (b) (4)	08 Oct 2020 14:55:20

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4)	08 Oct 2020 14:55:20

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:22:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 14:55:20

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '10 Sep 2020'	Kelly Woodell (b) (4)	08 Oct 2020 14:55:55
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Chest x-ray 1 view'	Kelly Woodell (b) (4)	08 Oct 2020 14:55:55

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4)	08 Oct 2020 14:55:55

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:22:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 14:55:55
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '12 Sep 2020'	Kelly Woodell (b) (4)	08 Oct 2020 14:56:23
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Chest x-ray 2 views'	Kelly Woodell (b) (4)	08 Oct 2020 14:56:23

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Diagnostic (DIAGNOSTIC)'	Kelly Woodell (b) (4)	08 Oct 2020 14:56:23

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:22:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4)	08 Oct 2020 14:56:23

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered '09 Sep 2020'	Kelly Woodell (b) (4)	22 Oct 2020 18:11:30
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Cardiac Ablation'	Kelly Woodell (b) (4)	22 Oct 2020 18:11:30

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered 'Medical History (MH)'	Kelly Woodell (b) (4)	22 Oct 2020 18:11:30

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 11:22:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:41:08
User entered empty.	Kelly Woodell (b) (4)	22 Oct 2020 18:11:30

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered '10 Sep 2020'	Kelly Woodell (b) (4)	10 Nov 2020 16:46:47
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Echocardiogram'	Kelly Woodell (b) (4)	10 Nov 2020 16:46:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Adverse Event (AE)'	Kelly Woodell (b) (4)	10 Nov 2020 16:46:47

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 11:22:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered empty.	Kelly Woodell (b) (4)	10 Nov 2020 16:46:47
	(b) (4)	

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered '11 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 16:58:02

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 11:22:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Incentive spirometer'	Kelly Woodell (b) (4)	10 Nov 2020 16:58:02

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 11:22:22

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Other (OTHER)'	Kelly Woodell (b) (4)	10 Nov 2020 16:58:02

US3822015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 11:22:22

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'Prophylaxis'	Kelly Woodell (b) (4)	10 Nov 2020 16:58:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	(b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	(b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
User entered '12/Sep/2020 14:53'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:22:22

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)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered '1'	(b) (4), (b) (6)	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	(b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
User entered '17/Sep/2020 11:31'	System	17 Sep 2020 15:31:11

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:22:22

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)
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:28:27
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 15:31:11

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
User entered '29/Sep/2020 10:28'	System	29 Sep 2020 14:28:35

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:22:22

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)	24 Nov 2020 21:48:51
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered '1'	(b) (4), (b) (6)	29 Sep 2020 14:28:35

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
User entered '06/Oct/2020 14:05'	System	06 Oct 2020 14:05:09

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:22:22

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)	24 Nov 2020 21:48:51
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 15:33:18
User entered '1'	(b) (4), (b) (6)	06 Oct 2020 14:05:09

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	(b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
User entered '08/Oct/2020 15:33'	System	08 Oct 2020 15:33:49

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:22:22

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)	24 Nov 2020 21:48:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 12:58:39
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 15:33:49

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
User entered '13/Oct/2020 12:58'	System	13 Oct 2020 12:58:51

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 11:22:22

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)	24 Nov 2020 21:48:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 18:55:36
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 12:58:51

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	(b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
User entered '23/Oct/2020 18:55'	System	23 Oct 2020 18:55:47

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 11:22:22

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)	24 Nov 2020 21:48:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 18:55:55
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 18:55:47

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'USA-US126-2020-MRNA-1273-P301000002'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'Yes (Y)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 18:52:54
User entered 'No (N)'	System	12 Sep 2020 18:50:43

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Christina'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
Amendment Manager: User entered 'Kennelly'	System	14 Sep 2020 21:44:17

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:32
User closed query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:36:29
Query 'Kindly update the rest of the fields on this page. Thank you.' answered with 'updated' (Site from CRA).	Kelly Woodell (b) (4)	05 Nov 2020 01:08:36
Un-reviewed for Safety.	(b) (4)	05 Nov 2020 01:08:31
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User opened query 'Kindly update the rest of the fields on this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 15:05:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:35
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:37
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
Un-reviewed for Safety.	System	05 Nov 2020 20:52:37
DataPoint Un-verified.	System	05 Nov 2020 20:52:37
User entered empty.	System	05 Nov 2020 20:52:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 20:52:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:36:40
Un-reviewed for Safety.	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Nov 2020 01:08:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:04:55
User entered empty.	Krishna Shah (b) (4)	05 Oct 2020 19:39:23

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 14:05:46
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:47:20
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:30:55
User entered 'US' (non-conformant).	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:22:22

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	05 Nov 2020 20:52:37
User entered '7'	System	23 Oct 2020 18:55:47
User entered '6'	System	13 Oct 2020 12:58:51
User entered '5'	System	08 Oct 2020 15:33:49
User entered '4'	System	06 Oct 2020 14:05:09
User entered '3'	System	29 Sep 2020 14:28:35
User entered '2'	System	17 Sep 2020 15:31:11
User entered '1'	System	12 Sep 2020 18:53:02

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 11:22:22

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:51
User entered '05/Nov/2020 20:52'	System	05 Nov 2020 20:52:37

US3822015

Folder: SAE USA-US126-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 11:22:22

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)	24 Nov 2020 21:48:51
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 20:52:37